EPA Pesticide Petition No. 6F4650

DP BARCODE: D268860

CASE: 287240 DATA PACKAGE RECORD DATE: 09/08/00
SUBMISSION: S585062 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: TOLERANCE PET ACTION: 230 F PET RAW AGRI COMMO
CHEMICALS: 119202 Trichoderma harzianum Rifai (variety); KRL-AG2 (st %

ID#: 6F04650
COMPANY:
PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL
PM TEAM REVIEWER: SHANAZ BACCHUS 703-308-8097 ROOM: CS1 5TH FL
RECEIVED DATE: 09/12/95 DUE OUT DATE: 05/09/96

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 268860 EXPEDITE: N DATE SENT: 09/28/95 DATE RET.: 03/07/96
CHEMICAL: 119202 Trichoderma harzianum Rifai (variety); KRL-AG2 (strain)
DP TYPE: 001
CSF: N LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 03/06/96
DIV : BPPD	03/06/96	03/07/96	NEGOT DATE: / /
BRAN: BPPD-IO	03/06/96	03/07/96	PROJ DATE: / /
SECT: IO	03/06/96	03/07/96	
REVR : SBACCHUS	03/06/96	03/07/96	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Review FR template for publication.

* * * DATA PACKAGE EVALUATION * * *

incomplete FR template needs revision

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

---------- Forwarded by Phil Hutton/DC/USEPA/US on 04/07/99 02:24 PM ----------

envsubset
04/07/99 11:42 AM
Please respond to epa-pest2@valley.rtpnc.epa.gov
To: epa-pest2@valley.rtpnc.epa.gov
cc:
Subject: Trichoderma harzianum KRL-AG2 (ATCC #20847) or Strain

[Federal Register: April 7, 1999 (Volume 64, Number 66)]
[Rules and Regulations]
[Page 16856-16860]
>From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr07ap99-13]

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300823; FRL-6070-3]
RIN 2070-AB78

Trichoderma harzianum KRL-AG2 (ATCC #20847) or Strain T-22; Revision of Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY:This regulation establishes an exemption from the requirement of a tolerance for residues of the microbial pesticide active ingredient Trichoderma harzianum KRL-AG2 (ATCC #20847) also known as strain T-22 when applied/used as seed treatments, on cuttings and transplants, or as soil

[[Page 16857]]

treatments and certain foliar applications. Bioworks Inc., 122 North

Genesee Street, Geneva, New York 14456 submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This rule allows a revision of the existing exemption from tolerances for seed treatments (40 CFR 180. 1102) for residues of Trichoderma harzianum KRL-AG2 (ATCC #20847, also known as strain T-22) to include additional food commodities. This regulation eliminates the need to establish a maximum permissible level for residues of Trichoderma harzianum KRL-AG2.

DATES: This regulation is effective April 7, 1999. Objections and requests for hearings must be received by EPA on or before June 7, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300823], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ``Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees) and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300823], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP-300823]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington,

DC 20460. Office location, telephone number, and e-mail address: 9th fl., Crystal Mall #2 1921 Jefferson Davis Hwy., Arlington, VA, 703-308-8097, bacchus.shanaz@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 22, 1997 (62 FR 34390) (FRL-5737-2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) announcing the filing of a pesticide tolerance petition by Bioworks Inc., 122 North Genesee Street, Geneva, New York 14456. This notice included a summary of the petition prepared by the petitioner Bioworks, Inc. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of Trichoderma harzianum KRL-AG2 (ATCC #20847) in/on all food commodities. There were no comments received in response to the notice of filing.

I. Risk Assessment and Statutory Findings

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ``safe." Section 408(c)(2)(A)(ii) defines ``safe" to mean that ``there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ``ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue..." Additionally, section 408 (b)(2)(D) requires that the Agency consider ``available information" concerning the cumulative effects of a particular pesticide's residues and ``other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

This pesticide is currently registered for seed treatments for which an exemption from tolerance exists for certain raw agricultural commodities (40 CFR 180.1102). In PR Notice 95-3, June 7, 1995, the Agency included this active ingredient in a list of low risk pesticides qualifying for reduced restricted entry intervals (REI) depending on the exposure and risk posed to workers. The data submitted to support the initial registration of this product includes three acute rat studies, an acute oral toxicity/pathogenicity study, an acute pulmonary toxicity/pathogenicity study and an acute intravenous toxicity study. The active ingredient is classified as Toxicity Category IV on the basis of those studies. A waiver was granted for the acute dermal toxicity studies.

T. harzianum KRL-AG2 (ATCC #20847) is not known to produce any compounds or metabolites of health concern. This organism controls plant disease by competing with plant pathogens for root and foliar surfaces for the establishment of fungal colonies and by mycoparasitism. There are no known genotoxic or reproductive effects.

III. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from groundwater or surface water and exposure through

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pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

Trichoderma harzianum is a naturally occurring fungus. This strain is a typical member of that species. There is no evidence that it presents any risk to animals or humans. This species is present in many different types of environments worldwide. Because of its ubiquitous nature all humans and animals have some natural exposure to the organism. Proposed application methods, uses, and application rates is not likely to result in a sustained increase in the population levels of this organism beyond the naturally occurring background levels of Trichoderma harzianum.

5

A. Dietary Exposure

Dietary exposure is not expected from the use of this microbial pesticide as labeled. The microbial pesticide can be removed by peeling, washing, cooking and processing. Therefore, risk and exposure to humans, infants and children is likely to be minimal.

1. Food. Dietary exposure to the microbial pesticide is likely to occur. The lack of acute oral toxicity/pathogenicity, and the ubiquitous nature of the microbial, support the exemption from the requirement of a tolerance for this active ingredient.

2. Drinking water exposure. The microorganism Trichoderma harzianum KRL-AG2 (ATCC #20847) is common in the soil and may be found in aquatic habitats. Drinking water is not being screened for Trichoderma harzianum KRL-AG2 (ATCC #20847) as a potential indicator of microbial contamination. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to Trichoderma harzianum KRL-AG2 (ATCC #20847) through drinking water. Therefore, the potential of significant transfer to drinking water is minimal to nonexistent. However, even if negligible oral exposure should occur through drinking water, the Agency concludes that such exposure would present no risk due to the lack of toxicity and the ubiquitous nature of the microbe.

B. Other Non-Occupational Exposure

Dermal and inhalation exposure and risk to adults, infants and children via treated lawns or recreational areas are likely if the pesticide is used as labeled. However, the pesticide is a naturally occurring microbe and is ubiquitous in the environment. Based on the low toxicity potential as evidenced by the data submitted, the microbial pesticide active ingredient is likely to pose a minimal to nonexistent dermal or inhalation hazard if used as labeled.

IV. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ``available information'' concerning the cumulative effects of a particular pesticide's residues and ``other substances that have a common mechanism of toxicity.'' There are several strains of Trichoderma spp. registered at this time. While these strains may produce similar metabolites, the likelihood of adverse cumulative effects via a common mechanism of toxicity is likely to be minimal based on the lack of toxicity/pathogenicity potential of the active ingredients.

V. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. In this instance, EPA believes there are reliable data to support the conclusion that there are no threshold effects of concern to infants, children and adults when Trichoderma harzianum KRL-AG2 (ATCC #20847) is used as labeled. As a result, the provision requiring an additional margin of exposure does not apply.

VI. Other Considerations

A. Endocrine Disruptors

EPA does not have any information regarding endocrine effects of this microbial pesticide at this time. The Agency is not requiring information on the endocrine effects of this pesticide at this time; and Congress allowed 3 years after August 3, 1996, for the Agency to implement a screening and testing program with respect to endocrine effects.

B. Analytical Method(s)

The registrant has submitted data and analytical methods to identify potential contaminants and to assure that they are within regulatory levels. All batches containing potential human pathogens are to be destroyed.

C. Codex Maximum Residue Level

There are no Codex maximum residue levels for this active ingredient.

D. Conclusions

The Agency has concluded that the use of this pesticide will not pose any adverse health effects to the U.S. population, infants and children, because of the low toxicological profile. As a result, EPA establishes an exemption from tolerance requirements pursuant to FFDCA section 408(j)(3) for Trichoderma harzianum KRL-AG2 (ATCC #20847) in/on all food commodities.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ``object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d)and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by June 7, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ``ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ``when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services

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Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more

of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP-300823] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ``ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations(59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected

officials and other representatives of State, local, and tribal governments ``to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of

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Indian tribal governments ``to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of

Representatives and the Comptroller General of the United States prior to publication of the rule in the Federal Register. This rule is not a ``major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 24, 1999.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division. Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a), and 371.

2. Section 180.1102 is revised to read as follows:

Sec. 180.1102 Trichoderma harzianum KRL-AG2 (ATCC #20847) strain T-22; exemption from requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biofungicide Trichoderma harzianum KRL-AG2 (ATCC #20847); also known as strain T-22 when applied in/or on all food commodities.

[FR Doc. 99-8637 Filed 4-6-99; 8:45 am]
BILLING CODE 6560-50-F

[Federal Register: March 29, 1996 (Volume 61, Number 62)]
[Notices]
[Page 14098-14099]
>From the Federal Register Online via GPO Access [wais.access.gpo.gov]

ENVIRONMENTAL PROTECTION AGENCY
[PP 6F4650/PF646; FRL-5357-3]

Trichoderma harzianum Rifai Strain KRL-AG2; Notice of filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: EPA has received a petition (PP 6F4650) for a revision of the current

[[Page 14099]]
exemption from the requirement of tolerances for Trichoderma harzianum Rifai strain KRL-AG2 (40 CFR 180.1102) to include all raw agricultural commodities. The request was filed by TGT Inc., 122 North Genesee Street, Geneva, N.Y. 14456.
DATES: Written comments, identified by the docket control number [PP 6F4650/PF646], must be submitted to EPA by April 29, 1996.
ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by docket number [PP 6F4650/PF646]. No CBI should be submitted through e-mail. Electronic comments on this notice of filing may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in the SUPPLEMENTARY INFORMATION section of this document.

Information submitted as a comment concerning this document may be

claimed confidential by marking any part or all of that information as ``Confidential Business Information'' (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington DC 20460. Office location and telephone number: 5th Floor, CS #1, 2805 Jefferson Davis Hwy., Arlington, VA, 703-308-8097; e-mail address: bacchus.shanaz@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

PP 6F4650. This notice announces that EPA has received from TGT Inc., 122 North Genesee Street, Geneva, N.Y. 14456, a notice of filing under section 408 of the Federal Food, Drug, and Cosmetic Act (21 (U.S.C. 346a) for pesticide petition (PP) 6F4650 to amend 40 CFR part 180 to revise the current exemption from the requirement of tolerances for the microbial pesticide Trichoderma harzianum Rifai strain KRL-AG2. The current exemption from the requirement of a tolerance (40 CFR 180.1102) is established for residues of this biofungicide in or on beans (green and dry), cabbage, corn (field and sweet), cotton, cucumbers, peanuts, potatoes, sorghum, soybeans, sugar beets, and tomatoes when used as a fungicide for the treatment of seeds of these crops in accordance with good agricultural practices.

This petition requests that the current exemption from tolerances be revised to include all raw agricultural commodities which have been sprayed or otherwise treated with Trichoderma harzianum Rifai strain KRL-AG2. The pesticide is to be applied as seed treatment, for pot filling, as a dip for cuttings and transplants, as an in-furrow spray, and as a sprayable formulation. Rates of application vary from 4 to 8 ounces per hundredweight of seed, and up to 10 pounds per acre (in furrow) for row crops at planting. Field and greenhouse crops may be sprayed at rates of 1 pound per acre and up to 5 applications per year.

A record has been established for this notice of filing under docket number [PP 6F4650/PF646] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal

holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments can be sent directly to EPA at:
opp-Docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this notice of filing, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in ``ADDRESSES'' at the beginning of this document.

List of Subjects

Environmental Protection, Agricultural commodities, Pesticides and Pests, Reporting and recordkeeping requirements.

Dated: March 19, 1996.

Janet L. Anderson
Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 96-7743 Filed 3-28-96; 8:45 am]
BILLING CODE 6560-50-F

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Non-Target Plant Data Requirements to Support Use of *Trichoderma harzianum* Strain T-22 (KRL-AG2) as a Seed Treatment for Wheat

FROM: Mike Mendelsohn, Microbiologist 8/15/2000
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division

THRU: Chris Wozniak, Ph.D., Biologist 8/15/2000
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division

Zigfridas Vaituzis, Ph.D., Microbiologist 8/17/2000
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division

TO: Shanaz Bachus, Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division

Phil Hutton, Chief
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division

MICROBIAL AGENT & OPP PC CODE : *Trichoderma harzianum* Strain T-22 (KRL-AG2); (119202)

FILE SYMBOLS: 68539-3, 68539-4

DP BARCODE: D267042

I. BACKGROUND

On 10/29/1998, BBPD concluded that the use of *T. harzianum* strain T-22 on sugarcane, pechay, rice, mushrooms, kiwi, tobacco, wheat, barley, oats, lemon, apples and chickpea were not supported due to reports regarding the potential of phytotoxicity and/or pathogenicity to these

crops from *T. harzianum*. In particular, a report in the literature indicated that *T. harzianum* produced (-)-harzianopyridone that caused wheat coleoptile growth inhibition[1]. Reports were summarized by Dr. Robert G. Butz of ChemReg International, LLC and submitted to BPPD to support the use Strain T-22 as a seed treatment for wheat on 5/23/2000.

II. DISCUSSION

The public literature cited by Dr. Butz and relevant conclusions regarding Strain T-22 are listed below.

"In field plots, ...*Trichoderma harzianum* (Bioworks T-22) ... increased significantly (over nontreated) the seedling emergence and grain yield of wheat..."[2]

"...*Trichoderma harzianum* (Bioworks T-22) ... applied to wheat seed, naturally infected by *Fusarium graminearum*, resulted in increased seedling emergence compared to non-treated seeds..."[3]

Treatment of wheat seeds with Strain T-22 increased stands relative to the untreated control.[4]

"Seed treatment had no statistically significant effect on plant stand, grain yield, or test weight."[5]

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[1]Cutler, H. and Jacyno, J. " Biological Activity of (-)-Harzianopyridone Isolated from *Trichoderma harzianum*" Agricultural Biological Chemistry 55 (10), 2629-2631, 1991.

[2]Da Luz, W.C., G.C. Bergstrom and C.A. Stockwell. 1998. Seed-applied bioprotectants for control of seedborne*Pyrenophora tritici-repentis* and agronomic enhancement of wheat. Canadian Journal of Plant Pathology 19:384-386.

[3]Da Luz, W.C., C.A. Stockwell and G.C. Bergstrom. 1997. Seed microbiolization for control of *Fusarium* species in cereals. Proceedings of National Fusarium Head Blight Forum, November 1997.

[4]Harman, G.E., A.G. Taylor and T.E. Stasz. 1989. Combining Effective Strains of *Trichoderma harzianum* And Solid Matrix Priming to Improve Biological Seed Treatments. Plant Disease 73:631-637.

[5]Kawamoto S.O., G.C. Bergstrom, W.J. Cox and D.J. Otis. 1998. Effects of Seed Treatment on Disease and Yield of Winter Wheat in New York, 1998. APS Biological and Cultural Tests. Cornell Univ., Ithaca, NY.

III. CONCLUSION

Based on the specific reports on Strain T-22 in the literature, we conclude that the proposed seed treatment use of *T. harzianum* strain T-22 on wheat is unlikely to cause any adverse effects on wheat. However, the use of *T. harzianum* strain T-22 on sugarcane, pechay, rice, mushrooms, kiwi, tobacco, barley, oats, lemon, apples and chickpea continue to be unsupported due to reports regarding the potential of phytotoxicity and/or pathogenicity to these crops from *T. harzianum*.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Non-Target Organism Data Requirements for BioWorks, Inc.'s T-22 G Biological Fungicide and T-22WP Containing the Microbial Fungicide *Trichoderma harzianum* Strain KRL-AG2

FROM: Mike Mendelsohn, Microbiologist
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division

Mike Mendelsohn 10/29/98

THRU: Douglas Gurian-Sherman, Ph.D., Plant Pathologist
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division

10/29/98

Zigfridas Vaituzis, Ph.D., Microbiologist
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division

Zigfridas Vaituzis 10/29/98

TO: Shanaz Bachus, Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division

Phillip O. Hutton, Chief
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division

MICROBIAL AGENTS & OPP PC CODES : *Trichoderma harzianum* Strain KRL-AG2 (119202); Also Known as Strain T-22

EPA REGISTRATION NUMBERS: 68539-3, 68539-4

DP BARCODES: D237657

ACTION/STUDY TYPE: Action Code 330 - Technical New Food / Feed Use Amendment

I. Use Sites and Application Methods

T-22G Current	T-22G Proposed	T-22 Planter Box	T-22WP Proposed
	all raw agricultural commodities, food and fiber crops, ornamentals, landscape plants, and trees unless otherwise stated	SEED TREATMENT beans (green & dry), cabbage, corn (field & sweet), cotton, cucumbers, peanuts, sorghum, soybean, sugar beets, tomatoes, all ornamental crops 4-10 oz per hundredweight of seed	all raw agricultural commodities, food and fiber crops, ornamentals, landscape plants, and trees unless otherwise stated SEED TREATMENT 4-10 oz per hundredweight of seed
IN-FURROW SOIL TREATMENT - 10 lb/acre beans(green & dry), cabbage, corn (field and sweet), cotton, cucumbers, peanuts, potatoes, sorghum, soybean, sugar beets & tomatoes	IN-FURROW SOIL TREATMENT - 10 lb/acre		
BROADCAST APPLICATIONS TO TURF <u>Established Turf</u> - (usually up to 2 applications) 1-3 lbs/ 1000 ft^2 turf 40-60 lbs/acre for golf course fairways <u>New Turf Seedings</u> 1-4 lbs/ 100 ft^2 soil surface at time of grass seeding	BROADCAST APPLICATIONS TO TURF <u>Established Turf</u> - (usually up to 2 applications) 1-3 lbs/ 1000 ft^2 turf 40-60 lbs/acre for golf course fairways <u>New Turf Seedings</u> 1-4 lbs/ 1000 ft^2 soil surface at time of grass seeding Incorporate into the soil surface or cover with mulch along with grass seed.	1 to 3 lbs per 100 lbs of bulbs or cut potato pieces CUTTINGS OR BARE ROOTED TRANSPLANTS: ALL ORNAMENTAL CROPS, CABBAGE, TOMATOES, AND CUCUMBERS Dip cuttings or transplants into dry product or in a suspension of 1 1b product in 5 gallons of water.	0.03 to 3 lbs per 100 lbs of bulbs or cut potato pieces CUTTINGS OR BARE ROOTED TRANSPLANTS: Dip cuttings or transplants into dry product or in a suspension of 0.2 - 5 lbs product in 5 gallons of water.
GREENHOUSE SOIL AMENDMENT Cabbage, Tomatoes, Cucumbers, Ornamentals 1- 1½ lbs/yd^3 greenhouse soil or planting mixes in pots or planting beds	GREENHOUSE SOIL AMENDMENT 1- 3 lbs/yd^3 planting mixes 0.5 -7.5 lbs per 1000 ft^2 of bed by raking or tilling	GREENHOUSE POTTING MIX OR SOIL DRENCH: ALL ORNAMENTAL CROPS, CABBAGE, TOMATOES, AND CUCUMBERS: 3-6 0z per loose cubic yard greenhouse potting mix or soil	GREENHOUSE /NURSERY DRENCH FOR POTTING MIX OR SOIL 3 - 32 oz in 100 gallons of water applied 50-100 gallons per 800 ft^2 for seeding flats or shallow beds or pots; 100 gallons per 400 ft^2 for deeper beds or pots or ½ to 1 cup per pot. Application through low pressure watering nozzles, overhead boom type sprayers or sprinklers, or other drench watering systems.
TRANSPLANTS 1 - 8oz per planting hole for trees, shrubs, and other transplants	TRANSPLANTS 0.2 - 8oz per planting hole for trees, shrubs, and other transplants BROADCAST OR SIDE-BAND APPLICATION TO CROPS 10-60 lbs/acre BROADCAST APPLICATION TO SEEDING OR TRANSPLANT BEDS 0.5-7.5 lbs per 1000 ft^2	IN-FURROW SPRAY: BEANS (GREEN & DRY), CABBAGE, CORN, (FIELD & SWEET), COTTON, CUCUMBERS, PEANUTS, SORGHUM, SOYBEAN, SUGAR BEETS, TOMATOES, ORNAMENTAL CROPS 2-32 oz/acre HOME GARDEN	CHEMIGATION sprinkler, flood, etc. IN-FURROW SPRAY OR TRANSPLANT STARTER SOLUTION 2-32 oz/acre HOME GARDEN TURF SPRAY 2-16 oz per 1000 ft^2 FOLIAR AND FRUIT SPRAY 1-8 lbs per acre in 50-400 gallons

Proposed New Use Sites

° In-Furrow Soil Treatment - All Crops

° Greenhouse Soil Amendment - All Crops

° Seed Treatment - All Crops

° Cutting or Bare Rooted Transplants - All Crops

° Greenhouse Drench for Potting Mix or Soil - All Crops

° Granular Broadcast or Sideband Application - All Crops

° Granular Broadcast Application to Seeding or Transplant Beds - All Crops

° Nursery Drench for Soil or Potting Mix - All Crops

° Sprinkler and Flood Chemigation - All Crops

° Turf Spray

° Foliar and Fruit Spray - All Crops

II. Literature Searches

Attachment I highlights certain public literature provided by BioWorks , on file at EPA, or found during EPA's literature search. EPA's literature search consisted of one search for each organism using the organism's Latin binomial in Agricola, Medline, and Biological & Agricultural Index via FirstSearch on 8/4/97. Summary results follow. We recognize the variation that exists among different strains of *Trichoderma harzianmum* and that reports of pathogenicity in the literature for the species may not be pertinent to strain KRL-AG2. However, in the absence of data, we will assume that adverse literature reports for the species apply to strain KRL-AG2 unless the literature report or submitted data show otherwise.

A. Non-Target Plants

Reports indicate possible or confirmed phytotoxicity and/or pathogenicity of *T. harzianum* to apple fruit, rice, corn, sugarcane, pechay, tomato, mushrooms, lemon, kiwi, cotton, and tobacco. Beneficial myrorrhizal fungi of barley, oats, and soybean are reported as being adversely affected. In addition to reports in the literature, the American Phytopathological Society home page on the world wide web was accessed. Trichoderma foot rot of chickpea caused by

Trichoderma harzianum Rifai was listed on the common names of plant diseases list. However, we have been unable to confirm this through the literature.

- *T. harzianum* was shown to cause apple fruit rot. It has also been reported as providing biological control of apple dry rot caused by *Botritus cinerea* by spraying the flowers and has been reported as a promising biocontrol agent for apple tree seedlings. (See Attachment I, endnotes 61, 62 & 63)

- Culture filtrates of *T. harzianum* significantly inhibited germination and growth of rice, corn, and sugarcane. Pot experiments in corn and sugarcane demonstrated retarded root extension after inoculation with spore suspension. (See Attachment I, endnotes 44, 48 & 49)

- *T. harzianum* treatment of corn seedlings resulted in enhanced plant growth possibly due to the production of a growth-regulatory factor. Previous studies with *T. harzianum* showed pathogenicity to corn hybrids and necrotic lesions on roots and mesoocotyls. The differing corn reports "may be due to different environmental conditions, maize genotypes, or genetic variability of *Trichoderma* isolates within the same species complex." (See Attachement I, endnote 1)

- *T. harzianum* may have caused stunting and lodging of affected pechay and soybean but not of corn seedlings in the laboratory. Also, greenhouse tests using sterile soil may have demonstrated stem rotting to pechay after seeds were treated with *T. harzianum*. Stunting and yellowing of corn, tomato and pechay in plants grown in soil with *T. harzianum* may also have taken place. However, it is unclear from the abstract whether the mixture of *Trichoderma* species was tested as a mixture or separately. More information is needed to make a conclusion regarding pechay, soybean, corn, and tomatoes from these studies. (See Attachment I, endnote 51)

- Some *T. harzianum* strains are pathogenic to mushrooms. (See Attachment I, endnotes 27, 41, 69, 70, 73, 74, 77 & 80)

- *T. harzianum* is reported as being pathogenic to *Citrus limonum* (lemon). (See Attachment I, endnotes 57 and 59)

- *T. harzianum* may be pathogenic to kiwi. (See Attachment I, endnote 57)

- Regarding the beneficial mycorrhizal fungi, *T. harzianum* does not appear to adversely affect vesicular-arbuscular mycorrhiza in pot experiments using field soil and corn roots. However, *T. harzianum* negatively affected mycorrhizal formation in barley and oats and a commercial strain of *T. harzianum* suppressed vesicular-arbuscular mycorrhizal formation in soybean. (See Attachment I, endnotes 50, 65, 76 & 78)

- *T. harzianum* may be an important component of a cotton wilt complex along with the nematode *Meloidogyne incognita* and the fungi *F. oxysporum*. (See Attachment I, endnote 1)

- *T. harzianum* has been shown to induce extensive root necrosis in tobacco plants colonized by the nematode *Meloidogyne incognita*. (See Attachment I, endnote 1)

- *T. harzianum* produced (-)-harzianopyridone caused wheat coleoptile growth inhibition, corn leaf necrosis, as well as adverse effects in tobacco and beans. (See Attachment I, endnote 82)

B. Non-Target Insects

- In regards to the larvicidal activity of *Trichoderma harzianum* against the bark beetles *Scolytus scolytus* and *Scolytus multistriatus*, the authors of the paper concluded that "[a]lthough the results imply that *Trichoderma* spp. and *S. lignicola* may be useful biological control agents for bark beetles, the main problem for their field application is getting the fungi to the larvae which are under the bark. It seems unlikely that the antagonistic fungi will establish the type of infection that would spread throughout natural populations." "The presence of spores in the haemocoel suggests that the organsims establish a mycotic infection. (See endnote 42 in Attachment I for reference.)

- Described as a symbiotic fungi of the striped bark beetle. (See endnote 36 in Attachment I for reference.)

- Described as associated with forest bark engraving beetle *Ips calligraphus* but not found pathogenic in laboratory bioassay in the Philippines. (See endnote 37 in Attachment I for reference.)

- Possibly fed on by mites and collembolans. (See endnote 38 in Attachment I for reference.)

- Used in laboratory as food for Egyptian acarid mite. (See endnote 39 in Attachment I for reference.)

- Grazed on by mites when among fungi of infested onion bulbs. (See endnote 40 in Attachment I for reference.)

C. Honey Bee - Two reports of *T. harzianum* delivered to strawberry plants for *Botrytis cinerea* control were submitted. The first report concentrated on efficacy towards gray mold of the *T. harzianum* and did not report any adverse effects towards bees. Strain T-22

was tested, however observations on hive health were not made. The second report focused on a study assessing honey bee impacts from another strain of *T. harzianum*, strain T-39. While this report showed no significant difference between treated and control bees, significant mortality was observed in both treatment and control hives at the end of the experiment. (See endnotes 85 and 86 in Attachment I for reference.)

D. Avian

- Cassava root meal enriched with *T. harzianum* suggested for use in chicken diets. (See endnote 35 in Attachment I for reference.)

E. Freshwater Fish - No reports found.

F. Freshwater Aquatic Invertebrate

- Reported as part of the mycoflora of freshwater leeches in Egypt. (See endnote 30 in Attachment I for reference.)

G. Environmental Distribution

"Fungi of the genus *Trichoderma* are recognized as 'keystone or controller' organisms in forest soils due to their involvement in decomposition and nutrient cycling and their regulation of associated mycoflora." (See endnote 5 in Attachment I for reference.)

Trichoderma harzianum has been isolated from freshwater sites in Egypt and from freshwater leeches at those sites at concentrations as high as 7.4×10^3 CFU/l and 4.3×10^3 CFU/l respectively. (See endnote 30 in Attachment I for reference.)

In regards to the larvicidal activity of *Trichoderma harzianum* against the bark beetles *Scolytus scolytus* and *Scolytus multistriatus*, the authors of the paper concluded that "[a]lthough the results imply that *Trichoderma* spp. and *S. lignicola* may be useful biological control agents for bark beetles, the main problem for their field application is getting the fungi to the larvae which are under the bark. It seems unlikely that the antagonistic fungi will establish the type of infection that would spread throughout natural populations." (See endnote 42 in Attachment I for reference.)

Successful mycoherbicidal use in the field requires high inoculum concentration and long dew period "needed for germination and establishment of the pathogen." (See endnote 66 in Attachment I for reference.)

T. harzianum applied to sweet corn and soybean seeds were recovered from root surfaces 3-12 weeks after sowing at levels greater than 10^5 cfu/g of rhizosphere soil. (See endnote 46 in Attachment I for reference.)

In an experiment where corn soil was treated with *T. harzianum*, population densities were approximately 5 x 10^6 cfu/g air dried soil at innoculation, between $10^7$and 10^8 cfu/g at 10 days after innoculation, and then stable between $10^5$and 10^6 cfu/g air dried soil for the next 30 days. (See endnote 1 in Attachement I for reference.)

Chlamydospores probably important for survival of *Trichoderma harzianum* in the soil. (See endnote 45 in Attachement I for reference.)

T. harzianum one of the major species isolated from Malaysian tropical rain forest litter and soil at 25 degrees C. (See endnote 52 in Attachement I for reference.)

T. harzianum associated with Marram grass in Dutch coastal foredunes. Role as non-plant-pathogen not clearly set forth. (See endnote 54 in Attachement I for reference.)

T. harzianum found widely distributed in Indian (?) citrus orchards. (See endnote 56 in Attachement I for reference.)

Isolated from cultivated and forest soil in Thailand. (See endnote 58 in Attachement I for reference.)

III. Adequacy of the Database and Risk Assessment Conclusions

A. Data Required

40 CFR Part 158.740 and the more recent July 1989 Subdivision M of the Pesticide Assessment Guidelines indicates that for the use patterns selected, the following nontarget organism data requirements must be satisfied either via the submission of adequate data or waiver request(s). Additionally, the Agency may require more information if deemed necessary.

	Subdivision M Guideline Reference No.	OPPTS Microbial Pesticide Test Guidelines
Avian Oral (Quail & Mallard)	154-16	OPPTS 885.4050
Freshwater Fish (Trout)	154-19	OPPTS 885.4200
Freshwater Aquatic Invertebrate	154-20	OPPTS 885.4240
Non-Target Plant	154-22	OPPTS 885.4300
Non-Target Insect	154-23	OPPTS 885.4340
Honey Bee	154-24	OPPTS 885.4380

B. General BPPD Response to BioWorks Rationale to Waive Non-Target Organism Studies

Since fish, plant, mammalian, non-target insect and bird pathogenicity are all well reported in the scientific literature; nontarget organism pathogenicity testing of fish, plants, wild mammals, non-target insects and birds is not necessary for a microbial pest control agent (MPCA) when (as confirmed by a thorough literature search): 1) the MPCA's natural environmental distribution includes the habitat of the nontarget organism species normally tested in Tier I pathogenicity studies, and 2) the MPCA has never been found in association with nontarget organism disease. The toxicity of an MPCA product formulation can be impacted by the parameters of the fermentation and also by post-fermentation processing. Toxicity, in addition to pathogencity, must be addressed due to the impact that the fermentation and the post-fermentation processing can have on the production, elimination or concentration of microbial toxins and metabolites.

C. Submitted Data

GRN	MRID #	Study	Status, Classification & Comments
154-16	412459-08	Avian Oral Toxicity/ Pathogenicity (Quail)	Acceptable. The study is scientifically sound and demonstrated an LD_{50} > 11,119 mg/kg. Each treated bird received a dose of 2222 mg/kg or approximately 9 x 10^8 cfu/kg each day for five days.
N/A	N/A	7/23/98 BioWorks Letter Re: Observations for Phytotoxicity During 1997 Research	See Attachment II.

D. Database and Risk Conclusions for New Uses Not Significantly Increasing Environmental Exposure

° In Furrow Soil Treatment - All Crops
° Greenhouse Soil Amendment - All Crops
° Seed Treatment - All Crops
° Cutting or Bare Rooted Transplants - All Crops
° Greenhouse Drench for Potting Mix or Soil - All Crops
° Nursery Drench for Potting Mix - All Crops

Use sites should not include **sugarcane, pechay, rice, mushrooms, kiwi, tobacco, wheat, barley, oats, lemon, apple and chickpea** until the reports regarding these plants and *T. harzianum* are satisfactorily addressed regarding the potential for phytotoxicity and/ or pathogenicity from the proposed uses.

One literature report raised potential concerns regarding the impact of this product **to tomatoes**. However, the abstract was not clear whether *T. harzianum,* another *Trichoderma* species, or a mixture of *Trichoderma* species were in soil causing stunting and yellowing of tomatoes. The July 23, 1998 summary by Bioworks of their 1997 research results indicated a lack of phytotoxicity to greenhouse tomatoes via foliar spray. Also, the currently approved uses include greenhouse soil amendment with tomatoes, tomato seed treatment, tomato cuttings, and in-furrow spray with tomatoes. No reports of phytotoxicity were included with this data package. Therefore, it is recommended that Bioworks confirm that they have not received any adverse reports regarding tomatoes and estimate the current tomato use level to support the current uses.

Literature reports raise potential concerns regarding the impact of this product to soybean, cotton, and corn. In-furrow treatments and seed treatments of **corn, cotton, and soybeans** are already approved uses. Therefore, it is recommended that Bioworks confirm that they have not received any adverse reports regarding corn, cotton, and soybeans and estimate the current use levels on these crops to support the current uses. Also, endnote 1 of Attachment I should be addressed regarding the variation in corn effects reported in the literature.

With the above unresolved exceptions, the risk to non-target organisms from the other proposed terrestrial uses in this section is minimal to nonexistent. No additional non-target data is required for the other proposed terrestrial use sites in this section.

E. Database Conclusions for Uses Increasing Environmental Exposure Over Seed Treatment

° Granular Broadcast or Sideband Application - All Crops
° Granular Broadcast Application to Seeding or Transplant Beds - All Crops
° Nursery Drench for Soil - All Crops
° Sprinkler and Flood Chemigation - All Crops
° Turf Spray
° Foliar and Fruit Spray - All Crops
° Granular Broadcast Applications to Turf (Already on Approved Label)

1. Avian

Given the natural and widespread occurrence of *T. harzianum* and the lack of reported avian pathogenicity, as well the lack of toxicity in the Bobwhite quail study where birds were dosed at 2,222 mg/kg/day for five days with no treatment related effects after 30 days; no additional testing is required to conclude that the risk to birds is minimal to nonexistent for all uses.

Data requirement satisfied.

2. Honey Bee

Two reports of *T. harzianum* delivered to strawberry plants via bees for *Botrytis cinerea* control were submitted. The first report concentrated on efficacy towards gray mold of the *T. harzianum* and did not report any adverse effects towards bees. Strain T-22 was tested, however observations on hive health were not made. The second report focused on a study assessing honey bee impacts from another strain of *T. harzianum*, strain T-39. While this report showed no significant difference between treated and control bees, significant mortality was observed in both treatment and control hives at the end of the experiment. No reports of pathogenicity to bees were found in the literature.

In order to confirm that the subject strain and manufacturing process do not pose a risk to bees via toxicity of metabolites or toxins, a 7 day *per os* study should be submitted which doses the bees for 24 hours and observes them for the remainder of the study. A sugar syrup(50% water/50% sucrose) should be mixed in a 90% to 10% weight per weight proportion with the technical grade material. Steps should be taken to ensure that the test material is well mixed into the sugar syrup and diet analysis should be performed to determine a measured concentration. Sampling should take place at different positions in the feeding vial. Sugar syrup(50% water/50% sucrose) should be used to feed the bees during the remainder of the study. A sugar syrup control should also be used. The use of an attenuated control is not necessary. It should be confirmed that the test material was manufactured in essentially an identical manner as the technical material in the proposed product.

Data requirement not satisfied.

3. Freshwater Aquatic Invertebrate

For the terrestrial uses listed above, we note that the application methods mentioned above can result in aquatic exposure via spray drift and run-off, therefore a 21 -day toxicity/pathogenicity study (guideline reference number 154-20) is required. We suggest submitting a protocol prior to test initiation. Careful attention should be paid to maintaining an adequate measured concentration as microbial suspensions tend to settle out. We note that this study is required for the current turf approved uses as well. It should be confirmed that the test material was manufactured in essentially an identical manner as the technical material in the registered products.

Data requirement not satisfied.

4. Freshwater Fish

For the terrestrial uses listed above, we note that the application methods mentioned above can result in aquatic exposure via spray drift and run-off. Given the natural occurrence of *T. harzianum* in the freshwater aquatic environment and the lack of pathogenicity for fish reported in the literature, only toxicity testing is required. A 96-hour rainbow trout LC_{50} study conducted per guideline reference number 72-1 is required. We suggest submitting a protocol prior to test initiation. We note that this study is required for the current turf approved uses as well. It should be confirmed that the test material was manufactured in essentially an identical manner as the technical material in the registered products.

Data requirement not satisfied.

5. Non-Target Plant

Use sites should not include **sugarcane, pechay, rice, mushrooms, kiwi, tobacco, wheat, barley, oats, lemon, apples and chickpea** until the reports regarding these plants and *T. harzianum* are satisfactorily addressed regarding the potential for phytotoxicity and/ or pathogenicity from the proposed uses.

One literature report raised potential concerns regarding the impact of this product to **tomatoes.** However, the abstract was not clear whether *T. harzianum,* another *Trichoderma* species, or a mixture of *Trichoderma* species were in soil causing stunting and yellowing of tomatoes. The July 23, 1998 summary by Bioworks of their 1997 research results indicated a lack of phytotoxicity to greenhouse tomatoes via foliar spray. Also, the currently approved uses include greenhouse soil amendment with tomatoes, tomato seed treatment, tomato cuttings, and in-furrow spray with tomatoes. No reports of phytotoxicity were included with this data package. Therefore, it is recommended that Bioworks confirm that they have not received any adverse reports regarding tomatoes and estimate the current tomato use level to support the current uses.

Literature reports raise potential concerns regarding the impact of this product to **soybean, cotton, and corn**. In-furrow treatments and seed treatments of corn, cotton, and soybeans are already approved uses. Therefore, it is recommended that Bioworks confirm that they have not received any adverse reports regarding corn, cotton, and soybeans and estimate the current use levels on these crops to support the current uses. Also, endnote 1 of Attachment I should be addressed regarding the variation in corn effects reported in the literature.

Provided that the use sites are limited to terrestrial sites only and that the application methods are specifically limited to ground application in the product labeling with a statement such as "APPLY VIA GROUND APPLICATION ONLY" ; then for all other terrestrial use sites in this

section III.E.., no additional data is required to address nontarget plant risks and we conclude that the risk to nontarget plants would be minimal to nonexistent.

Data requirement satisfied provided use limitations implemented.

6. Non-Target Insect

Given the reported larvicidal activity of *Trichoderma harzianum* against the bark beetles *Scolytus scolytus* and *Scolytus multistriatus* and that "[t]he presence of spores in the haemocoel suggests that the organisms establish a mycotic infection."; a non-target insect toxicity/pathogenicity study performed on ladybird beetle is necessary to confirm a lack of pathogencity towards non-target insects. In addition, since the threatened valley elderberry longhorn beetle is present in riparian areas near certain vineyards (per conversation with Richard Marovich of CalEPA), a study on the toxicity/pathogenicity of strain KRL-AG2 to a beetle closely related to the valley elderberry longhorn beetle (*Desmocerus californicus dimorphus)* should be submitted. We suggest submitting a protocol for Agency review prior to initiating the study. Depending on the results of these studies, additional data may be necessary to assess the risk to other endangered or threatened beetles.

Data requirement not satisfied.

Attachment I - Summary of Public Literature Re: *Trichoderma harzianum* for Bioworks Products EPA Reg. Nos. 68539-3, -4; Including EPA Searches of AGRICOLA, MEDLINE, & BIOLOGICAL & AGRICULTURAL INDEX; Literature Reports Already on File at EPA; and BioWorks Submitted Papers

° Positive impact on growth in corn.[1]

° Positive impact on asparagus seed germination.[2 3]

° In Wisonsin; soils around apple trees, woodland soils immediately downhill from apple trees, and in virgin white pine forest were sampled for Trichoderma spp. They "...were enumerated on and recovered from dilution plates, containing a selective medium, at 8, 16, and 24 degrees C... [f]or most soils, significantly fewer colony forming units (cfu) of Trichoderma spp developed at 8 degrees C compared to 16 or 24 degrees C, which had similar numbers of cfu. Populations of Trichoderma spp varied significantly among soils at each incubation temperature and were not correlated with soil physical characteristics... Trichderma spp appear well adapted to soils associated with apple trees in Wisconsin."[4]

° "Fungi of the genus Trichoderma are recognized as 'keystone or controller' organisms in forest soils due to their involvement in decomposition and nutrient cycling and their regulation of associated mycoflora."[5]

° Produces various antibiotics, membrane-modifying peptides, and enzymes.[6 7 8 9 10 11 12 13 14 15 16 17 18 19]

° Produces harzianum A, a new trichothecene.[20]

° Has larvicidal activity.[21]

° Potential involvement with peritonitis.[22]

° Produces harziphilone and fleephilone, potential drugs for HIV.[23]

° "[t]he parallel formation and synergism of hydrolytic enzymes and antibiotics may have an important in the antagonistic action of *T. harzianum* against fungal phytopathogens."[24]

° "Different classes of cell wall degrading enzymes produced by the biocontrol fungis *Trichoderma harzianum* and *Gliocladium virens* inhibited spore germination of *Botrytis cinerea* in a bioassay and *in vitro*.[25]

° Trichokindins were found to induce Ca(2+)-dependent catecholamine secretion from bovine adrenal medullary chromaffin cells.[26]

° "Based on these molecular biology data, group2 isolates, which are aggressive colonizers of mushroom compost, could be clearly distinguished from isolates belonging to the other 2 groups."[27]

° *Trichoderma harzianum* P1 spores produced via submerged fermentation are different than those produced by aerial mycelium.[28]

° Electrophoretic karyotyping methods exist for *Trichoderma harzianum*.[29]

° Associated with freshwater leeches.[30]

° Assocaited with urea-formaldehyde foam insulation. Health effects potential?[31]

° Interaction with plants.[32]

° Microhabitat in soil.[33]

° Possible cause of apple decay in storage.[34]

° Cassava root meal enriched with *T. harzianum* suggested for use in chicken diets.[35]

° Described as a symbiotic fungi of the striped bark beetle. Slovenia[36]

° Described as associated with forest bark engraving beetle *Ips calligraphus* but not found pathogenic in laboratory bioassay in the Philippines.[37]

° Fed on by mites and collembolans?[38]

° Used in laboratory as food for Egyptian acarid mite.[39]

° Grazed on by mites when among fungi of infested onion bulbs.[40]

° One slow to spore strain is reported as the cause of "an undescribed and potentially harmful mushroom disease."[41]

° Regarding the larvicidal activity "The presence of spores in the haemocoel suggests that the organsims establish a mycotic infection."[42]

° "The antibiosis ... of ***T. *** ***harzianum*** T42 with low antibiotic activity was increased by ammonium tartrate or NH4NO3."[43]

° ...[t]he unbalance of soil fungi could lead to the predominance of *Fusarium oxysporum* and *Trichoderma harzianum*, producers of phytotoxic substances, and might be responsible for the poor growth of sugarcane...Bioassay showed that the culture filtrates of *F. oxysporum* and ***T.*** ***harzianum*** in Hoagland's nutrient solution plus 1.5% sucrose for 3 weeks significantly inhibited germination and growth of rice, ***corn***, and sugarcane..."[44]

° Chlamydospores probably important for survival of *Trichoderma harzianum* in the soil.[45]

° Trichoderma harzianum applied to sweet corn and soybean seeds were recovered from root surfaces 3-12 weeks after sowing at levels greater than 10^5 cfu/g of rhizosphere soil.[46]

° Trichoderma harzianum, when applied via seed treatment, protects corn from *Fusarium spp.*.[47]

° Culture filtrates of *Fusarium oxysporum* and *Trichoderma harzianum* significantly inhibited germination and growth of rice, maize and sugarcane. Fungal metabolites significantly inhibited respiration and metabolic processes of sugarcane cells. [48,49]

° *Trichoderma harzianum and T. hamatum* do not appear to adversely affect vesicular-arbuscular mycorrhiza in pot experiments using field soil and maize roots.[50]

° *Trichoderma harzianum is* potential pathogen of pechay, tomato, soybean, and corn. However, a reprint of the article is necessary to confirm this as the abstract discussed several *Trichoderma* species.[51]

° *T. harzianum* one of the major species isolated from Malaysian tropical rain forest litter and soil at 25 degrees C.[52]

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° "The production of antibiotics may, therefore, be more important than that of chitinolytic enzymes in conferring superior biocontrol properties to ***T***. ***harzianum***."[53]

° *T. harzianum* associated with Marram grass in Dutch coastal foredunes. Role as non-plant-pathogen not clearly set forth.[54]

° Enzyme activity not always correlated to biocontrol capability.[55]

° *T. harzianum* found widely distributed in Indian (?) citrus orchards.[56]

° "Applied as spray treatments to the fruits, these fungi partially controlled *Botrytis cinerea* in strawberry and kiwifruit, *Fusarium oxysporum* in potato and *Alternaria citri* in lemon. *Trichoderma* significantly controlled artificially inoculated *B. cinerea* in strawberry but was ineffective against latent infections. Several strains of *Trichoderma* were pathogenic to kiwifruit and lemon."[57]

° Isolated from cultivated and forest soil in Thailand.[58]

° Pathogenic to *Citrus limonum*?[59]

° *Trichoderma spp.* promising as a biocontrol agent for disease on apple tree seedlings.[60]

° Cause of apple fruit rot.[61]

° "Biological control of dry eye rot of apple caused by B. cinerea was obtained by spraying the flowers with a conidial suspension of the antagonistic fungus Trichoderma harzianum.[62]

° *T. harzianum* reported as not being able to germinate below 5 degrees C.[63]

° Enzymes and antibiotics may work synergistically in *T. harzianum* biocontrol.[64]

° Vesicular-arbuscular mycorrhiza formation with *Glomus mosseae* in soybean was suppressed in a container system with a commercial strain of *Trichoderma harzianum*. *T. harzianum* also induced accumulation of large amounts of the phytalexin glyceollin in the roots.[65]

° When applied in an invert emulsion, *T. harzianum* colonized soybean. "Besides retaining water for spore germination, the invert emulsion may cause cuticular damage, allowing leaf penetration by the fungi. The emulsion could also suppress the plants' elicited responses to infection."[66]

° *T. harzianum* improved plant vigor and root mass development in tomato transplants via a peat plug.[67]

° Trifluralin-induced chlorosis in soybeans.[68]

° In a widespread outbreak of green mould mainly affecting bagged compost in Ireland, three strains of *T. harzianum* were found virulent towards mushrooms.[69]

° *T. harzianum* competitor of shiitake mushrooms.[70]

° Growth rates of *Trichoderma* varies substantially within and among species.[71]

° *T. harzianum* among dominant mycoflora in maize field soil (Italian?).[72]

° *T. harzianum* isolated from shitake (*Lentinus edodes)* logs was induced to produce lytic enzymes against cell walls of basidiomycetes.[73]

° "Lentinus edodes, cultivated on logs, is the most important edible mushroom in Japan." *T. harzianum* distrurbed mycelial growth of *L. edodes* via antibiotic activity.[74]

° *T. harzianum* grazed by soil arthropods.[75]

° *T. harzianum* negatively affected mycorrhizal infection in barley and oats.[76]

° Strain Th2 of *T. harzianum* causes severe attacks of green mould with yield losses in mushroom crops of 30% or more.[77]

° A strain of *T. harzianum* did not negatively impact colonization of maize roots by vesicular-arbuscular mycorrhiza in pot experiments.[78]

° *T. harzianum* has an optimum growth temperature of 28 degrees C. It can produce thick-walled chlamydospores that survive 24 hours at 60 and 63 degrees C.[79]

° *T. harzianum* is a pathogenic fungus that attacks shiitake mushroom (*Lentinula edodes).*[80]

° "Harzianum A [1] showed no cytotoxicity against baby hamster kidney cells at concentrations up to 1 μg/ml (13), no antimicrobial activity against *E. coli, B. subtilis, M. latens,* or *S. aureus*at 1 mg/ml, and modest activity against the fungi *C. albicans* and *S. cerrevisiae* at 100 μg/ml in a well-diffusion assay."[81]

° *T. harzianum* applied to soybean seeds sown in the field gave yield increases over untreated seeds.[46]

° *T. harzianum* produced (-)-harzianopyridone caused wheat coleoptile growth inhibition, corn leaf necrosis, as well as adverse effects in tobacco and beans.[82]

° *T. harzianum* is reported as being effective against Botytis grey mold on greenhouse cucumber and tomato, apple, grape, and chickpea foliage. Trichodex and an australian *T. harzianum* isolate both did not provide protection to chickpea seeds that were innoculated with *Botrytis cinerea* in the form of improved seedling establishment.[83]

° *T. harzianum* strain KRL-AG2 soil treatment helped reduce *Fusarium* crown and root rot in tomato in Florida.[84]

° *T. harzianum* strain 1295-22 was applied via honey bees to strawberries. No adverse effects to the bees were reported. However, it is not clear to what extent hive and bee health were evaluated as the study was primarily evaluating Botrytis control in strawberries.[85]

° *T. harzianum* strain T-39 was evaluated for its impact on honey bee survival. Bees were exposed via special application trays at hive entrances. Bee survival and hive weight were similar for both control and treatment. However, there was a substantial loss in hive weight.[86]

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Ms. Kim Reisch
BioWorks, Inc.
122 north Genesee Street
Geneva, NY 14456

Dear Ms. Reisch:

EPA Reg. Nos. 68539-3, 68539-4: Proposed New Use Sites
***Trichoderma harzianum* strain T-22 (active ingredient # 119202)**
Ecological Effects: Published literature and MRID 41245908

The Agency has reviewed your data submissions regarding ecological effects of the microbiological pesticide, *Trichoderma harzianum* strain T-22 (active ingredient # 119202) and has made certain decisions about the proposed new uses of your subject fungicides. In order to make the decisions, the scientific team has considered the proposed new use sites in two categories:

Category A: Sites not significantly increasing environmental exposure over the currently registered seed treatments (see Section D of the enclosed Non-target organism review).

Such sites are:

- In-furrow soil treatment - all crops
- Greenhouse soil amendment - all crops
- Seed Treatment - all crops
- Cutting or bare rooted transplants - all crops
- Greenhouse drench for potting mix or soil - all crops
- Nursery drench for potting mix - all crops

Category B: Sites which are likely to increase environmental exposure over the currently registered seed treatments label uses (see Section E of the enclosed Non-target organism review).

Such sites are:

- Granular broadcast or sideband application - all crops
- Granular broadcast application to seeding or transplant beds - all crops
- Nursery drench for soil - all crops
- Sprinkler and flood chemigation - all crops
- Foliar and Fruit Spray - all crops
- Turf Spray

For both Category A and B sites, **sugarcane, pechay, rice, mushrooms, kiwi, tobacco, wheat, barley, oats, lemon, apple, and chickpea** cannot be registered until the reports regarding the potential phytotoxic effects of *T. harzianum* strain T-22 on these plants are satisfactorily addressed. and/or pathogenicity

Category A Sites

The Category A sites can be added to the label pending

- your confirmation that you have not received adverse effects reports as a result of ~~seed treatments of~~ uses on tomatoes, corn, cotton and soybeans. You must also submit estimates of the current use levels on these crops to support these uses and an explanation regarding the variation in corn effects reported in the literature (see Endnote 1 of Attachment 1 in the Non-target organism review);
- submission of an amended label to include the recommended sites ~~for~~ and subsequent Agency approval; (move to make 1st bullet.)

CONCURRENCES

SYMBOL	7511W	7511C	7511C	7511C				
SURNAME	BACCHUS	KOUGH	VAITUZIS	Mendelsohn				
DATE	12/2/98	12/9/98	12/15/98	12/23/98				

- publication and acceptance of the Federal Register Notice to amend of 40 CFR 180.1102 to include these use sites.

Category B sites

For the Category B use sites, environmental exposure and risk are likely to be greater than expected for the currently registered seed treatment sites. The Agency has evaluated the database which was submitted for the seed treatments and has decided that further data are required.

Guideline 154-16: Avian Oral Toxicity/Pathogenicity

No treatment related effects were observed on the bobwhite quail treated for 5 days at 2222 mg/kg/day. No additional data are required to conclude that the risk to birds is minimal to non-existent.

Guideline 154-19: Freshwater Fish

For these Category B sites, spray drift and run-off may increase exposure levels to freshwater fish. A 96-hr rainbow trout LC_{50} study is required in order to assess the potential effects of the pesticide to freshwater fish. Submission of a protocol prior to initiation of studies is highly recommended. If your intention is to include application to freshwater aquatic sites, data will be required on both the rainbow trout and the bluegill. Additional guideline requirements must be met for application of this pesticide to estuarine environments.

Guideline 154-20: Freshwater Aquatic Invertebrate

To evaluate the effects on aquatic invertebrates, a 21-day toxicity/pathogenicity study to determine the effects on Daphnia is required. It is recommended that you submit a protocol prior to initiating the study. You must also confirm that the test material for this study is manufactured in essentially an identical manner as the technical material in the registered products (see enclosed Non-target organism review).

Guideline 154-22: Non-target plant

The pesticide must **not** be applied to **sugarcane, pechay, rice, mushrooms, kiwi, tobacco, wheat, barley, oats, lemon, apple, and chickpea** until the reports regarding the potential phytotoxic effects of *T. harzianum* strain T-22 on these plants are satisfactorily addressed.

Also, the statement "Apply via Ground Application Only" must appear on the label and the uses limited to terrestrial use sites.

Guideline 154-24: Honey bee

The results from the reports on honeybee are unclear. In order to confirm that the pesticide poses no hazard to honeybees, a 7 day study as described in the Non-target organism review is required.

Category B sites cannot be added to the label until the data outlined above and the submitted product chemistry data are reviewed and determined to satisfy guideline requirements.

In the meanwhile, to process your request, the Agency requires an amended label to include the Category A sites and the information discussed above. If you have any questions regarding these matters, do not hesitate to call Shanaz Bacchus at 703-308-8097.

Sincerely,

Janet L. Andersen, Ph. D.
Director
Biopesticides and Pollution
Prevention Division

Encl. Non-target organism review

T-22 Planter Box
Biological Fungicide

ACTIVE INGREDIENT	
Trichoderma harzianum Rifai strain KRL-AG2	1.15%
OTHER INERT INGREDIENTS	98.85%
TOTAL	100.00%

*Contains at least 1.0 x 10^7 colony forming units per gram dry weight.

KEEP OUT OF REACH OF CHILDREN
CAUTION
STATEMENT OF PRACTICAL TREATMENT

In case of contact, flush eyes with plenty of water. Get medical attention if irritation persists.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Avoid contact with skin or eyes. Avoid breathing dust. Do not store near food or feed.

PERSONAL PROTECTIVE EQUIPMENT

Applicators and other handlers must wear: a) long sleeved shirt and long pants; b) shoes plus socks; c) when dumping or opening bags, or other operations where dusts may be created, wear goggles and OSHA TC-21C dust mask for biological products.

Follow manufacturer's directions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should: wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water.

GENERAL INFORMATION

T-22 Planter Box is a biological fungicide for control of root diseases. The active ingredient is a beneficial microbe, *Trichoderma harzianum* strain T-22. When applied as an inoculant to seeds, transplants or other propagative material, or to the soil or greenhouse potting mix, T-22 actively grows onto plant roots as they develop and provides prolonged protection against plant pathogens such as *Pythium, Rhizoctonia and Fusarium*. T-22 Planter Box can be used alone or in conjunction with certain chemical fungicides; consult compatibility charts for detailed information. Where early season seed and seedling diseases are expected, T-22 Planter Box should be used with chemically treated seed for stand establishment and prolonged root disease control.

Note: T-22 Planter Box contains live spores of a beneficial microbe. For best results, T-22 Planter Box should be stored below 80 degrees Fahrenheit and used without prolonged storage. T-22 becomes active when soil temperatures are above 50 degrees Fahrenheit and is not effective while soils remain cold. Control is more effective in neutral or acidic soils than in alkaline soils.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected workers may be in the area during application. For any requirement specific to your state or tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do no enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry in treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, are: a) coveralls; b) waterproof gloves; c) shoes plus socks.

SEED TREATMENT: BEANS (GREEN & DRY), CABBAGE, CORN (FIELD & SWEET), COTTON, CUCUMBERS, PEANUTS, SORGHUM, SOYBEAN, SUGAR BEETS, TOMATOES AND ALL ORNAMENTAL CROPS: T-22 Planter Box biological fungicide is applied to seeds as an inoculant at planting for prolonged protection against root diseases. For large, smooth seeds such as soybean or dry bean, apply 4-6 ounces per hundredweight (oz/cwt) of seed. For smaller or rougher seed such as cotton or corn, apply 6-8 oz/cwt. For sweet corn, apply 8-10 oz/cwt. To assure uniform application, add half the required amount of T-22 Planter Box to half the seed in the hopper, mix with a wooden paddle, and then add the remaining seed and T-22 Planter Box. For maximum seed protection, especially in cold soils, apply T-22 Planter Box to commercially treated seed such as seed treated with Apron and or Demosan for stand establishment.

FOR VEGETATIVELY PROPAGATED CROPS SUCH AS POTATOES AND BULBS: Dust at 1 - 3 lbs to 100 lbs bulbs or cut potato seed pieces. Apply to seed pieces or bulbs so surfaces are thoroughly covered with dust in a convenient container or drum treater. All surfaces, knives, and other equipment used to cut and plant potatoes should be thoroughly sterilized before cutting and planting and at regular intervals. Treat cut surfaces of sprouted potatoes immediately after cutting The cut and treated seed pieces should be held for a week or more at cool temperature and high relative humidity to promote suberization, however, they may be planted immediately.

FOR CUTTINGS OR BARE ROOTED TRANSPLANTS: ALL ORNAMENTAL CROPS, CABBAGE, TOMATOES, AND CUCUMBERS: Dip cuttings or transplants in T-22 Planter Box dry powder or in a suspension of 1 lb T-22 in 5 gal water. Plant treated cuttings or translants in potting mix or soil in the usual manner.

GREENHOUSE POTTING MIX OR SOIL DRENCH: ALL ORNAMENTAL CROPS, CABBAGE, TOMATOES, AND CUCUMBERS: Suspend T-22 Planter Box in sufficient water to achieve uniform application and apply at a rate of 3 - 6 oz per cubic yard (loose) of greenhouse potting mix or soil. T-22 Planter Box can be applied through low pressure watering nozzles such as fan nozzles or other watering systems.

IN-FURROW SPRAY: BEANS (GREEN & DRY), CABBAGE, CORN (FIELD & SWEET), COTTON, CUCUMBERS, PEANUTS, SORGHUM, SOYBEAN, SUGAR BEETS, TOMATOES AND ALL ORNAMENTAL CROPS: Apply as an in-furrow spray at a rate of 2 oz - 32 oz/acre in sufficient water to achieve uniform application.

HOME GARDEN: ALL BEANS (GREEN & DRY), CABBAGE, SWEET CORN, CUCUMBERS, PEANUTS, SOYBEAN, SUGAR BEETS, TOMATOES AND ALL ORNAMENTAL CROPS For control of plant root diseases of vegetable and ornamental plants. Treat seeds with one teaspoon of T-22 Planter Box dust to one packet of seeds (1/4 to 1 oz) by shaking seeds and T-22 Planter Box together in a small container before planting. For drench application to seeds, mix 1 to 3 tablespoons of T-22 Planter Box per gallon of water and apply to 25 ft of planting furrow before covering the seeds with soil. For transplants, mix 1 to 3 tablespoons of T-22 Planter Box

per gallon of water and apply to roots and soil at transplanting. For established beds, apply as a drench (1 to 3 tablespoons per gallon per 100 Sq. ft.). This product is designed for application to seeds, plant roots and soil for control of plant root diseases and not for spray application to foliage or fruit.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: Store in a cool dry place. Do not freeze or expose to temperature above 80 degrees Fahrenheit. Do not store for prolonged periods. Keep container tightly closed when not in use.

NOTICE TO BUYER AND SELLER: Seller warrants that this product conforms to the description on the label and is reasonable fit for the purposes stated on the label when used and stored in accordance with directions under normal conditions of use. This warranty does not extend to use of this product contrary to conditions not reasonably foreseeable by the Seller, and Buyer and User assume the risk of any such use. Seller disclaims all other warranties express or implied, including any warranty of fitness or merchantability. Seller shall not be liable for consequential, special or indirect damages resulting from use or handling of this product and seller's sole liability and buyer's and user's exclusive remedy shall be limited to refund of the purchase price.

This product is sold only for uses stated on its label. No express or implied license is granted to use or sell this product under any patent in any country except as specified.

Country: United States of America

US Patent No. 5,260,213

EPA Reg. No. 68539-4
EPA Est. No. 068539-NY-001

Net Contents:
Lot No.

TGT, Inc.
122 North Genesee Street
Geneva, New York 14456

United States
Environmental Protection
Agency

Office of Pesticides and Toxic Substances
Office of Pesticide Programs (TS-7505C)
Washington, DC 20460

EPA Pesticide Fact Sheet

Name of Chemical: Trichoderma harzianum Rifai Strain KRL-AG2
Reason for Issuance: Registration of New Biological
Date Issued: November 1990
Fact Sheet Number:

1. Description

Generic Name: Trichoderma harzianum Rifai Strain KRL-AG2

Trade Names: F-Stop Biological Fungicide Concentrate and F-Stop Biological Fungicide-Seed Protectant

EPA Shaughnessy Code: 128903

Year of Initial Registration: 1990

Pesticide Type: Biofungicide

U.S. and Foreign Producers: Eastman Kodak Company
343 State Street
Rochester, New York 14650

2. Use Patterns and Formulations

Application sites: The manufacturing use product (MP) is for use only in the formulation of fungicides. The end-use product (EP) is for use in the control of damping-off and seed rot diseases caused by Pythium species on beans (green and dry), cabbage, corn (field and sweet), cotton, cucumbers, peanuts, potatoes, sorghum, soybeans, sugar beets, and tomatoes.

Types of formulations: Both products are identical and are powdered formulations containing 98% of the active ingredient. The active ingredient is a genetically modified strain of Trichoderma harzianum derived by protoplast fusion of two auxotrophic mutants of Trichoderma.

Types and methods of application: The EP is a seed treatment applied as a water-based slurry or in combination with pigments, carriers and/or adjuvants approved for coating seed through standard slurry or mist type commercial seed treating equipment.

Application rate: The EP is applied at the rate of 5 ounces of product per 100 pounds of seed.

3. Science Findings

Summary Science Statement:

The toxicological data which were submitted for this active ingredient included reports of an acute oral toxicity/pathogenicity study, an acute pulmonary toxicity/pathogenicity study, and an acute intravenous toxicity/pathogenicity study. The studies were performed using rats. All studies were classified as acceptable. The review of these studies indicated that the biofungicide is not toxic to, infective in, or pathogenic to rats by oral, pulmonary or intravenous routes of exposure.

A request that acute dermal toxicity testing be waived for this biofungicide was made based on the fact that the parent organism is wide spread and innocuous in nature. To support the waiver, additional information on worker exposure was requested. Information on the history of the production process, a summary of sources of operator exposure and the number of exposure hours for a typical employee were submitted. The major potential source of worker exposure occurred during the fermentation process. No workers have shown evidence of dermal sensitivity to the organism and at other steps in the manufacturing process no indication of adverse effects were shown. Based on this information and the results of the acute studies, the acute dermal toxicity testing was waived because there is little likelyhood of acute effects from dermal exposure.

A primary eye irritation study was conducted on rabbits. The Trichoderma harzianum strain initially caused slight irritation to the eyes but no irritation was noted at 7 days after treatment. No incidents of hypersensitivity in humans have occurred during the development of the products.

The company was also requested to identify any sources of bacterial contamination and the steps in the manufacturing process where contamination might occur to ensure the absence of pathogenic microorganisms and/or toxins. No human or animal pathogens were detected in any of the production batches of the products.

To support the lack of adverse effects on wildlife, an avian oral pathogenicity/toxicity study on bob white quail was submitted which indicated that the test organism is practically nontoxic to terrestrial avian species by ingestion. The

requirement for tests on aquatic birds was waived because it is not expected that the fungus will enter the aquatic environment since its only use is as a seed treatment. Data requirements for evaluating adverse effects on freshwater fish and invertebrates, estuarine and marine organisms, nontarget plants and insects and honey bees were waived. The seed treatment use pattern makes it unlikely that Trichoderma would enter aquatic environments, contact nontarget plant species or that honey bees or other insects would be exposed to the organism.

Because only minimal exposure, if any, to nontarget organisms may occur from the use of this biofungicide as a seed treatment, there is not expected to be a "may effect" situation with regard to endangered species.

Data for environmental fate (Tier II) are not required for this biofungicide because no more than negligible environmental exposure associated with the seed treatment use is likely and the initial (Tier I) tests were waived or not required.

Chemical Characteristics:

Property	MP and EP
Color	yellow-green
Physical state	powder
Odor	vinegar
Density/bulk density	fluffed - 28.8 lbs/cu ft. packed - 43.6 lbs/cu ft.
pH	6.17
Storage stability	184 days at 20°C
Viscosity	N/A
Miscibility	N/A
Corrosion characteristics	N/A

Toxicological Characteristics:

Acute effects: Data were submitted for acute toxicity/pathogenicity as determined in oral, pulmonary and intravenous tests. Data were classified acceptable. The tests indicated that the product was not toxic to, infective in or pathogenic to rats.

Other toxicity information: Information was submitted which demonstrated that no human or animal pathogens were detected during the manufacturing process. Information was included on the history of the production process, a summary of sources of operator exposure and number of exposure hours for typical

employee. No hypersensitivity or other toxicological effects attributable to working with the organism were reported.

Ecological Effects:

Data on the ecological effects of the biofungicide were included only for an avian oral pathogenicity/toxicity study on bob white quail. The test organism was practically nontoxic to terrestrial avian species by ingestion. Data requirements for all other ecological effects testing were waived based on the nature of the fungus and the facts that it is unlikely that the organism will enter aquatic environments and minimal exposure would be likely due to the seed treatment use pattern.

4. Benefits

The use of the end-use product will be beneficial in the control of damping-off and seed rot diseases of seedling plants which may be a source of economic loss by reducing the stand of plants in the field. The availability of a biological fungicide would provide a less toxic alternative to the currently registered chemical seed treatments.

5. Tolerance Assessment

An exemption from the requirement for a tolerance for residues of Trichoderma harzianum Rifai Strain KRL-AG2 on beans, (green and dry), cabbage, corn (field and sweet), cotton, cucumbers, peanuts, potatoes, sorghum, soybeans, sugar beets, and tomatoes when used as a seed treatment in accordance with good agricultural practices was requested. Since testing of the biofungicide showed not evidence of effects which would be of toxicological concern, an exemption will be granted.

6. Summary of Major Data Gaps

No data gaps exist for this active ingredient.

Contact Person at EPA

Susan T. Lewis
Product Manager (21)
Fungicide-Herbicide Branch
Registration Division (H-7505C)
Environmental Protection Agency
401 M St., SW.
Washington, DC 20460

TGT Inc

Biological Technologies for the 21st Century

September 7, 1995

S BACHUS
242

BY FEDEX

Mr. Robert Torla
OPP BPPD H7504C
Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

SUBJECT: Revision of Exemption from Tolerance for Trichoderma harzianum strain KRL-AG2

Dear Mr. Torla:

Enclosed is a petition to revise an exemption from tolerance (40 CFR 180.1102) and a request for refund of the petition and refund request fees, sent directly to you as we discussed. The petition has also been sent to the document processing desk, as you directed.

The required petition fee has been sent to the EPA, Headquarter Accounting Branch, Pittsburgh, PA (photocopy attached). The fee for the request for refund is included with the materials sent to the document processing desk (photocopy enclosed).

Thank you for your assistance with this petition and refund request. As I explained on the phone today, we need to revise the exemption and revise our product registrations to satisfy our marketing partners, and time is of the essence.

Very truly yours,

Thomas E. Stasz

Thomas E. Stasz
VP Technology Development
& Legal Affairs

What is ATCC Culture #? 20476?

TES/km
encl.

122 North Genesee Street, Geneva, New York 14456
phone (315) 781-1703 ◊ (315) 781-1793 fax

TGT Inc

Biological Technologies for the 21st Century

September 7, 1995

Document Processing Desk (PETN)
Office of Pesticide Programs (H7504C)
Environmental Protection Agency
401 M Street S.W.
Washington, DC 20460

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Attn: Mr Robert Torla

SUBJECT: Request for Refund of Petition Fee (for Exemption from Tolerance Petition) and for Refund of Request Fee

Dear Mr. Torla:

TGT, Inc. has submitted a petition, dated September 7, 1995 (copy attached) for revision of an Exemption from Tolerance for a biological fungicide, and TGT, Inc.has paid the Petition Fee of $11,150.00 (photocopy of check attached). TGT hereby requests a refund of the Petition Fee.

Also, a check for $1,500 is enclosed in payment of this request for refund as required by 40 CFR 180.33 (m). We hereby request a refund of this latter Request Fee as well.

Refund of these fees is justified and is in the public interest. A Petition Fee was paid when the original exemption from tolerance was submitted in 1989. The current Petition is merely to revise the exemption from tolerance, as was suggested by the Agency. All significant information pertaining to the present revision has already been reviewed by the agency and is available in the Data Evaluation Record. Payment of a fee at the present time to revise the exemption from tolerance amounts to a double fee. The present petition to revise the exemption from tolerance is basically a housecleaning step and will avoid repeated requests to the Agency as the registrations for end use products are expanded. We are attempting to obtain a broader exemption from tolerance, as perhaps should have been done initially.

122 North Genesee Street, Geneva, New York 14456
phone (315) 781-1703 @ (315) 781-1793 fax

The subject of the Petition to revise the exemption from tolerance is a widespread and innocuous soil fungus, Trichoderma harzianum strain KRL-AG2. Originally registered several years ago, this fungus has been extensively tested for environmental and toxicological safety, and all concerns by the Agency have been addressed. The benign nature of this biocontrol fungus indicates that little additional review by the Agency will be required, and that a refund of the Petition Fee is therefore justified.

It is also critically important for the development of biological fungicides for the Agency to support emerging companies by granting fee refunds. Much of the effort and expense of developing and registering biological fungicides is being expended by emerging companies, and petition fees are a significant obstacle. Biologicals can significantly reduce chemical pesticide use for plant disease control, but only if companies are able to meet formidable obstacles, including registration costs.

The petitioner, TGT Inc, is a new company formed to get biological fungicides developed by university research out into the real world. The subject of the petition is a potentially widely useful biological fungicide, Trichoderma harzianum strain KRL-AG2. Refund of the petition fee for revising the exemption will remove a major barrier in our efforts to make this biological fungicide available.

We also note that an increasing number of biological materials are entering the market without registration or safety testing by using the label "inoculant" instead of "pesticide". We do not approve of this development in the biological pesticide industry, and feel it is important for products to be registered at the Federal and state levels. Refund of the Petition and Refund Request Fees by the Agency will support our efforts to comply with all regulatory requirements and help us to compete with these "inoculant" materials.

Sincerely,

Thomas E. Stasz

Thomas E. Stasz
Vice President for Technology Development
& Legal Affairs

TES/kam
Enclosure

BANK MONEY ORDER

096044

REMITTER TGT Inc,
Refund Request Fee

DATE Sept. 9, 1995

50-264/213

PAY TO THE ORDER OF ****** U.S. Environmental Protection Agency *******

TOMPKINS COUNTY TRUST CO. $150.00 AND 00 CTS

P.O. BOX 460
ITHACA, NEW YORK 14851

Traci M Smith

⑈096044⑈ ⑆021302648⑆01 205⑈900003⑈

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TGT Inc

Biological Technologies for the 21st Century

September 7, 1995

Environmental Protection Agency
Headquarters Accounting Operations Branch
Office of Pesticide Programs
(TOLERANCE FEES)
PO Box 360277M
Pittsburgh, PA 15251

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Dear Sirs:

Enclosed is a certified check for $11,150.00 made payable to the Environmental Protection Agency in payment of the fee for a petition to revise an Exemption from Tolerance for the biological fungicide Trichoderma harzianum Rifai strain KRL-AG2 (EPA reg. no. 68539-1; current exemption at 40 CFR 180.1102).

Also enclosed is a copy of the petition dated September 7, 1995.

If there are questions, I can be reached at 315-781-1703.

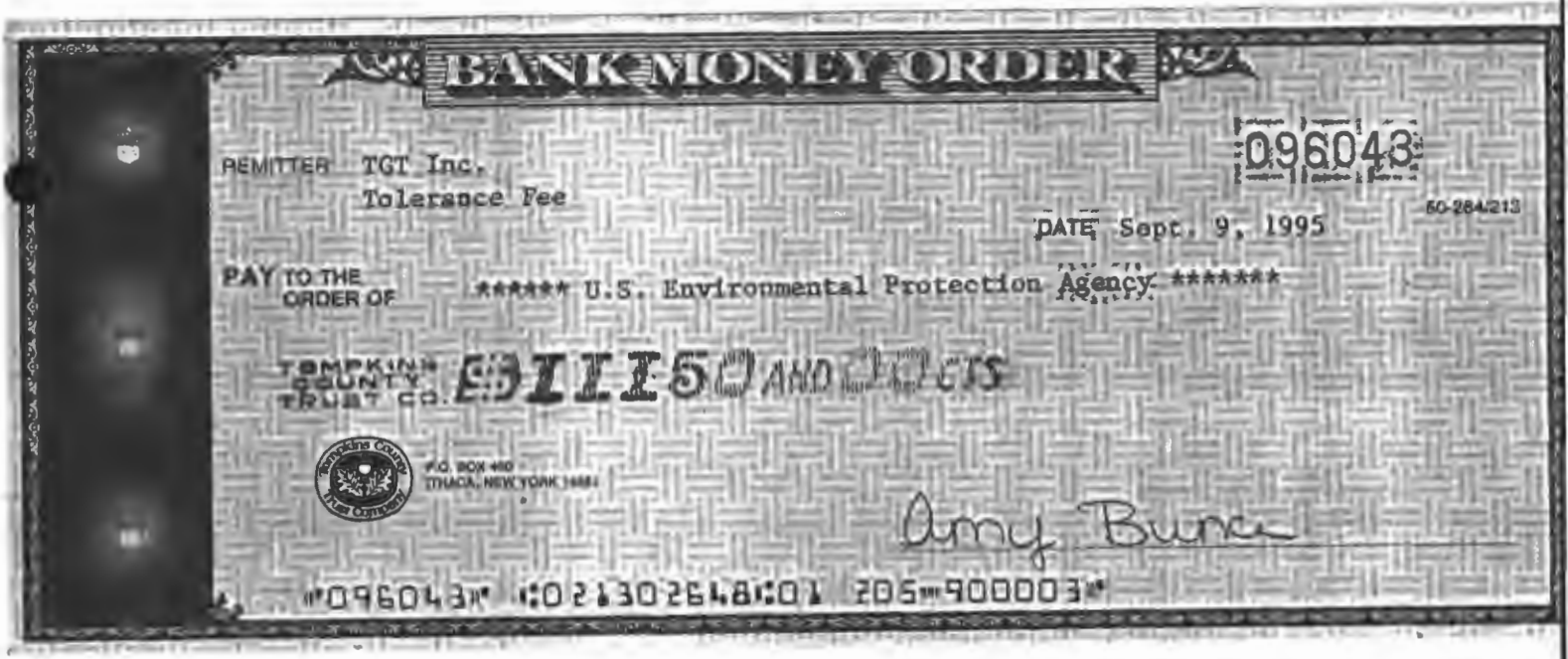
Sincerely,

Thomas E. Stasz

Thomas E. Stasz
Vice President for Legal Affairs

TES/kam
Enclosure

122 North Genesee Street, Geneva, New York 14456
phone (315) 781-1703 ◊ (315) 781-1793 fax



BANK MONEY ORDER

096043

REMITTER TGT Inc.
Tolerance Fee

DATE Sept. 9, 1995

50-264/213

PAY TO THE ORDER OF ****** U.S. Environmental Protection Agency *******

TOMPKINS COUNTY TRUST CO. FIFTY AND 00/100

P.O. BOX 460
ITHACA, NEW YORK 14851

Amy Burns

"096043" :021302648:01 205=900003"

TGT Inc

Biological Technologies for the 21st Century

September 7, 1995

Document Processing Desk (PETN)
Office of Pesticide Programs H7504C
Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Attn Mr. Robert Torla

SUBJECT: Revision of Exemption from Tolerance for Trichoderma harzianum strain KRL-AG2

Dear Mr. Torla:

The undersigned, Thomas E. Stasz, submits this petition on behalf of TGT Inc., pursuant to section 408 (d) (1) of the Federal Food, Drug, and Cosmetic Act with respect to the pesticide chemical Trichoderma harzianum Rifai strain KRL-AG2.

This is a petition to revise the current exemption from tolerance (40 CFR 180.1102) to include "in or on all raw agricultural commodities"and to include additional uses, as was recommended by Mr. Carl Grable of the Agency.

The required fee has been sent to the EPA, Headquarter Accounting Branch, Pittsburgh, PA (photocopy attached).

Petitioner: TGT, Inc, 122 North Genesee Street, Geneva, N.Y. 14456

By authority of: Rustin R. Howard, President

Attached hereto, in duplicate, and constituting a part of this petition, are the following:

A. The name, chemical identity, and composition of the pesticide chemical.

122 North Genesee Street, Geneva, New York 14456
phone (315) 781-1703 • (315) 781-1793 fax

B. The amount, frequency, and time of application of the pesticide chemical.

C. Full reports of investigations made with respect to the safety of the pesticide chemical.

D. The results of tests on the amount of residue remaining, including a description of the analytical method used.

E. Practicable methods for removing residue that exceeds any proposed tolerance.

F. Proposed tolerances for the pesticide chemical if tolerances are proposed.

G. Reasonable grounds in support of the petition.

If there are questions concerning this petition, please contact Thomas E. Stasz, Vice President for Legal Affairs, at 315-781-1703 or at TGT, Inc, 122 North Genesee St., Geneva, N.Y. 14456.

Very truly yours,

Thomas E. Stasz

Thomas E. Stasz
VP Technology Development
& Legal Affairs

TES/km

encl

2 of 13

Petition to Revise Exemption from Tolerance submitted Sept. 7, 1995 by Thomas E. Stasz, VP Legal Affairs, TGT Inc., 122 N. Genesee St., Geneva, NY 14456

SECTION A NAME, CHEMICAL IDENTITY AND COMPOSITION

NAME: *Trichoderma harzianum* Rifai strain KRL-AG2 (active ingredient)
EPA reg. no. 68539-1 (MUP)
EPA reg. no. 68539-2 (seed protectant)
EPA reg. no. 68539-3 (granular formulation)
EPA reg. no. 68539-4 (planter box formulation)

Current Exemption from Tolerance 40CFR 180.1102 (Petition submitted August 28, 1989 - see attached)

CHEMICAL IDENTITY & MANUFACTURING: Active Ingredient (studies previously submitted)

MRID #	GUIDELINE #	STUDY TITLE
41245901	151A-11	Manufacturing Process (F-Stop Biological Fungicide Concentrate)
41245902	151A-10, 151A-12 to 151A-17	Product Chemistry and Manufacturing Process (F-Stop Biological Fungicide Concentrate)

PRODUCT CHEMISTRY: Formulated products (studies previously submitted)

MRID #	STUDY TITLE
419009-01	Product Chemistry; Volume II(A), Product Identity and Manufacturing Process
419009-02	Product Chemistry; Volume II(B), Analytical Methods and Certification of Ingredient Limits
419009-03	Product Chemistry; Volume II(C), Physical and Chemical Characteristics - Color, Physical State, Odor, and pH

419009-04	Product Chemistry; Volume II(D), Physical and Chemical Characteristics - Density, Bulk Density or Specific Gravity
419009-05	Product Chemistry; Volume II(E), Physical and Chemical Characteristics - Storage Stability and Corrosion Characteristics

Note on manufacturing process (for granular formulation Reg. No. 68539-3)

An improved manufacturing process was submitted to the Agency on December 15, 1994 and approved on April 28, 1995 (letters attached).

[redacted]

COMPOSITION:

MUP (Reg. No. 68539-1) This material consists of dried biomass of *Trichoderma* grown by liquid fermentation. The composition is 98% active ingredient (dried biomass of *Trichoderma*) and 2% inert ingredients [redacted] The MUP contains at least 1 x 10^9 colony forming units of *Trichoderma* per gram dry weight.

SEED PROTECTANT

(Reg. No. 68539-2) This material is the same as the MUP - 98% active and 2% inert ingredients. The seed Protectant contains at least 1 x 10^9 colony forming units per gram dry weight.

GRANULAR

(Reg. No. 68539-3) This material consists of 1.15% active ingredient (*Trichoderma* grown on a solid matrix carrier) and 98.85% inerts [redacted]

4 of 13

[redacted]). The granular contains at least 1 x 10^7 colony forming units per gram dry weight.

PLANTER BOX

(Reg. No. 68539-4) This material consists of 1.15% active ingredient *Trichoderma* and 98.85% inerts [redacted] The Planter box material contains at least 1 x 10^7 colony forming units per gram dry weight.

SECTION B AMOUNT, FREQUENCY AND TIME OF APPLICATION

Seed treatment materials are applied at up to 8 oz. per hundred weight (CWT) of seed before planting.

Granular materials are applied:

Row crops (in furrow) 10 lbs./acre at planting
Turf (broadcast) up to 4 lbs./1000 sq. ft. and up to 3 applications per year.
Greenhouse (planting mix additive) up to 2 lbs./cubic yard applied at pot-filling.

Wettable powder materials:

Greenhouse (planting mix drench) up to 4 oz./cubic yard applied at pot-filling or to established plants, and up to two applications per crop.
Row crops (in-furrow spray) up to 1 lb./acre at planting.

Sprayable formulation:

Field and greenhouse crops up to 1 lb./acre and up to 5 applications/year.

Inert ingredient information may be entitled to confidential treatment

5 of 13

SECTION C SAFETY OF PESTICIDE CHEMICAL (MICROBIAL PEST CONTROL AGENT).

The following studies have been submitted previously to the Agency. The applicant hereby requests waiver of additional studies, if any.

Studies previously submitted:

MRID #	GUIDELINE #	STUDY TITLE
41245903	152A-1	Toxicology Studies -- Overview
41245904	152A-10	Acute Oral Toxicity/Pathogenicity in Rats
41245905	152A-12	Acute Pulmonary Toxicity/Pathogenicity in Rats
41245907	152A-14	Primary Eye Irritation/Infection Study in Rabbits
41245908	154A-16	Avian Oral Pathogenicity/Toxicity Test
41245909	None	Drying, Milling, and Assay of *Trichoderma* (Ricerca, Inc. report in support of Acute Oral Toxicity/Pathogenicity Study in Rats. Report No. 252994E)
41245910	None	Assay of *Trichoderma* Conidia (Ricerca, Inc. report in support of Acute Pulmonary and Acute Intravenous Toxicity/Pathogenicity Studies in Rats Report Nos. 252995F and 252996G)
41245911	None	Enumeration of *Trichoderma* AG2 (Ricerca, Inc. report in support of Primary Eye Irritation/Infection Study in Rabbits. Report No. 253030S)
41245912	None	Drying, Milling, and Assay of *Trichoderma* (Ricerca, Inc. report in support of Avaian Oral Pathogenicity/Toxicity Test. Report No. 252993D)

6 of 13

41245913	None	*Trichoderma harzianum* KRL-AG2: Analysis of Samples from Toxicology Batches for MPCA Potency, Bacterial Contamination, and Biocontrol Efficacy. (Cornell report in support of Acute Oral, Pulmonary, and Intravenous Toxicity Studies in Rats, Primary Eye Irritation Study in Rabbits, and Avian Oral Pathogenicity/Toxicity Test. Report Nos. 252994E, 252995F, 252996G, 253030S and 252993D)
41245914	None	Bioassay of *Trichoderma* (Ricerca, Inc. study in support of Acute Oral Toxicity/Pathogenicity Study in Rats. Report No. 252994E)
41245915	None	Bioassay of *Trichoderma* Conidia (Ricerca, Inc. study in support of Acute Pulmonary and Acute Intravenous Toxicity/Pathogenicity Studies in Rats. Report Nos. 252995F and 252996G)41245916
41245916	None	Bioassay of *Trichoderma* (Ricerca, Inc. study in support of Avian Oral Pathogenicity/Toxicity Test. Report No.282993D

SECTION D AMOUNT OF RESIDUES REMAINING AFTER APPLICATION:

Fungi in the genus *Trichoderma* are common soil inhabitants, and any residues that may result from application of *T. harzianum* strain KRL-AG2 are not a significant concern. This fungus naturally colonizes roots of plants, and population levels decrease to background levels during intercrop periods.

Further, product chemistry and toxicology data previously submitted indicate no health or environmental hazards.

Studies previously submitted:

MRID #	GUIDELINE #	STUDY TITLE
41245902 Appendix	151A-10	Overwinter Survival of *Trichoderma harzianum* KRL-AG2
NA	151A-10	Effect of Seed treatment with *Trichoderma harzianum* strain KRL-AG2 on Mycorrhiza

7 of 13

SECTION E PRACTICABLE METHODS OF REMOVING RESIDUES

Residues will be limited and are not of concern due to the nature of *Trichoderma*, its toxicity, and use pattern. Residues are not likely to occur in the majority of crops because the fungus colonizes crop roots. Therefore, methods of removing residues from crops are not necessary. In cases where residues may occur on the surface, such as crops where edible portions are grown beneath the soil surface, no health or environmental hazards are expected based on product chemistry and toxicology data submitted, and based on the ubiquitous occurrence of these fungi in agricultural soils around the world.

SECTION F PROPOSED TOLERANCE

Because this product has exhibited no toxic or pathogenic effects, TGT, Inc. hereby requests an exemption from the requirement of a tolerance pursuant to section 408 (d) (1) of the Federal Food, Drug and Cosmetic Act with respect to the pesticide *Trichoderma harzianum* Rifai strain KRL-AG2 for the following commodities:

"in or on all raw agricultural commodities"

SECTION G REASONABLE GROUNDS IN SUPPORT OF THE PETITION

An exemption from tolerance was granted for this biocontrol fungus (40 CFR 180.1102) for certain food crops on the basis of considerable toxicological and other data and based on the widespread occurrence of *T. harzianum* fungi in agricultural soils. The present petition to extend the exemption from tolerance to uses "in or on all raw agricultural commodities" follows the same rationale. The Agency, in a facsimile letter from Mr. Carle Grable dated 4/19/94 recommended that the current exemption should be revised in this way (fax attached).

This particular strain of *T. harzianum* (strain KRL-AG2) has been widely tested. No phytotoxicity has been observed in testing on a wide range of crops, application methods, and conditions. The fungus does not interfere with other beneficial soil microbes, such as mycorrhizal fungi and root nodulating bacteria. Population levels decrease overwinter to background levels.

The toxicological data which have been submitted previously for the registration of the active ingredient *Trichoderma harzianum* include reports of acute oral and other toxicology studies, including wildlife studies with bobwhite quail. These reports show there is no indication of toxicity or pathogenicity. A request for a waiver of all other toxicological data requirements, if

8 of 13

any, is made based on the facts that *Trichoderma harzianum* is widespread in the environment, is innocuous, and the use patterns for these products are limited to non-aquatic uses. The acute oral toxicity /infectivity/pathogenicity studies are classified as core-minimum.

Trichoderma harzianum (KRL-AG2) does not grow at or above 37^{o}C and is not pathogenic in warm-blooded animals or birds. *Trichoderma harzianum* is not known to be pathogenic to plants or insects. This species is naturally occurring in soils throughout the world and is widely regarded as innocuous or beneficial. The proposed application method, use, and rates will not result in a sustained increase in population over naturally occurring background levels of *Trichoderma harzianum*. The proposed uses do not pose a "may effect" to any endangered or threatened animal or plant species.

Data for environmental fate are not triggered under current requirements for the proposed product since the organism is not a product of recombinant DNA technology.

The Agency issued a Pesticide Fact Sheet in November, 1990 describing this fungus as widespread and innocuous. In PR Notice 95-3, June 7, 1995, the Agency included this fungus in a list of low risk pesticides qualifying for reduced restricted entry intervals (REI's).

Use of this biocontrol fungus can reduce the need for chemical pesticides for plant disease control.

9 of 13

ATTACHMENT TO SECTION A

August 28, 1989

Ms. Susan Lewis
Environmental Protection Agency
Herbicide-Fungicide Branch
Office of Pesticide Programs
401 M Street S.W.
Washington, DC 20460

SUBJECT: KRL-AG2 (F-STOP Biological Fungicide)
EPA File Symbol 59441-Pending
Petition for an Exemption from Tolerance

Dear Susan:

Eastman Kodak Company submits this petition for an exemption from the requirement of a tolerance pursuant to section 408(d)(1) of the Federal Food, Drug, and Cosmetic Act with respect to the pesticide Trichoderma harzianum. Attached to this letter is Kodak's petition for a tolerance exemption. A certified check in the amount of $8,875 has already been forwarded to the Agency; a copy of the letter transmitting the check is attached.

The data submitted herein to support the petition in Volumes IV through IX is included in the Application for Registration for Manufacturing Use Product and End Use Product.

If you have any questions, please do not hesitate to contact me at (716) 724-6819.

Respectfully submitted,

Deborah A. Mourey

DAM:brm
tolexempt

Encl.

Deborah A. Mourey
Manager, Regulatory Affairs
Plant Agriculture

10 of 13

ATTACHMENT TO SECTION A

RECEIVED MAY 15 1995

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 28 1995

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

TGT, Inc.
Attn: Mr. Thomas E. Stasz
122 North Genesee Street
Geneva, NY 14456

Dear Mr. Stasz:

Subject: Revised Manufacturing Process
T-22G Biological Plant Protectant Granules
EPA Reg. No: 68539-3
Submission Date: April 27, 1995

The revised manufacturing process submitted is acceptable and copies of the revised Confidential Statements of Formula have been added to the file for the subject product registration.

Sincerely,

Janet L. Andersen

Janet L. Andersen, Acting Director
Biopesticides and Pollution
Prevention Division 7501W

11 of 13

TGT Inc

Biological Technologies for the 21st Century

September 7, 1995

Environmental Protection Agency
Headquarters Accounting Operations Branch
Office of Pesticide Programs
(TOLERANCE FEES)
PO Box 360277M
Pittsburgh, PA 15251

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Dear Sirs:

Enclosed is a certified check for $11,150.00 made payable to the Environmental Protection Agency in payment of the fee for a petition to revise an Exemption from Tolerance for the biological fungicide Trichoderma harzianum Rifai strain KRL-AG2 (EPA reg. no. 68539-1; current exemption at 40 CFR 180.1102).

Also enclosed is a copy of the petition dated September 7, 1995.

If there are questions, I can be reached at 315-781-1703.

Sincerely,

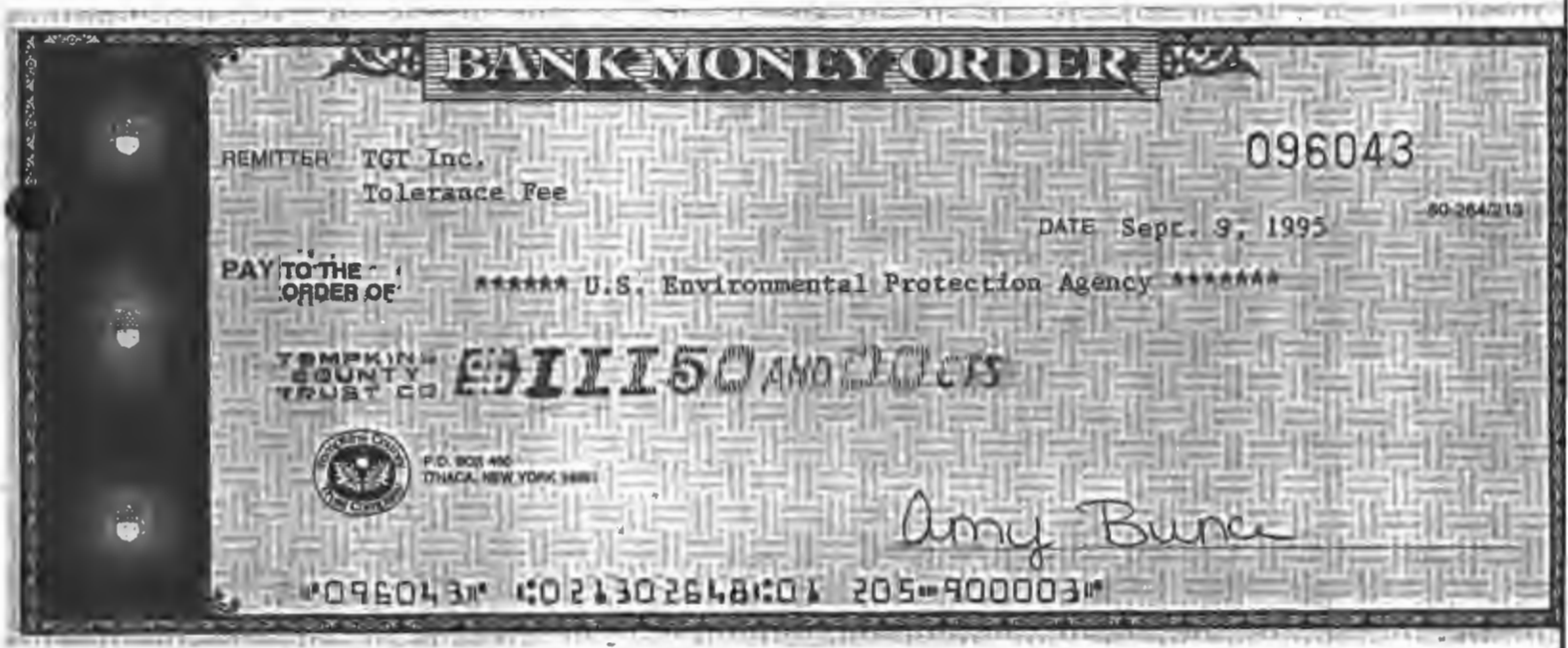
Thomas E. Stasz

Thomas E. Stasz
Vice President for Legal Affairs

TES/kam
Enclosure

12 & 13

122 North Genesee Street Geneva, New York [illegible]
phone (315) 781-1703 ✆ (315) 781-1793 [illegible]



BANK MONEY ORDER

096043

REMITTER TGT Inc.
Tolerance Fee

DATE Sept. 9, 1995

PAY TO THE ORDER OF ****** U.S. Environmental Protection Agency *******

TOMPKINS COUNTY TRUST CO

$ 150 AND 00 CTS

P.O. BOX 460
ITHACA, NEW YORK 14851

Amy Bunce

⑈096043⑈ ⑆021302648⑆01 205⑈900003⑈

13 of 13

BPPD PRAT ACTION CODING FORM

EPA REG./FILE SYMBOL 68539- ?

ACTION CODE 242

SUBMISSION BARCODE

PM 90: **Janet Andersen**

REVIEWER: S BACCHUS

Date on Application 9/ 7 /95

EPA Received Date 9 / 12 /95

PM Received Date 12 / 1 /95

Assigned in PRAT YES____ NO ✓ Did not know EPA Symbol

Completed By: Milwina Locklear Date 12-1-95

Rifaik RL-AG2 exists in for 40 CFR 180.1102 Revise current exemption from tolerance to include all crops.

****

FINAL ACTION:

3/5/96 Created FRN at Phil for OK

Response Code________

Response Date: / /95

MOS: _____ (1) Cite-All

_____ (4) Not Applicable

_____ (8) Selective

(1) What equipment used?

(2)

CRP:	Yes____	No____
Restricted Use:	Yes____	No____
Manufacturing Use:	Yes____	No____
Exclusive Use:	Yes____	No____

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL # of pages ► 4

To Thomas E Starz	From Shanaz Bacchus
Dept./Agency/Co TGT Inc	Phone # 703-308-8097
Fax # 315-781-1793	Fax # 703-308-7026

NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

Per your request

Attached is copy of FRN

Trichoderma harzianum Rifai

Strain KRL-AG2 as downloaded

from the Internet

[136] From: Phil Hutton 3/29/96 11:20AM (8127 bytes: 142 ln)
To: Anne Ball, Shanaz Bacchus
Subject: Trichoderma harzianum Rifai Strain KRL-AG2; Notice of filing
---------- Forwarded ----------
From: epa-pest@webster.rtpnc.epa.gov at IN 3/29/96 8:22AM (7903 bytes: 142 ln)
To: epa-pest@webster.rtpnc.epa.gov at IN
Subject: Trichoderma harzianum Rifai Strain KRL-AG2; Notice of filing
---------- Message Contents ----------

Text item 1: Text Item

Received: by ccmail from merlin.rtpnc.epa.gov
From epa-pest@webster.rtpnc.epa.gov
X-Envelope-From: epa-pest@webster.rtpnc.epa.gov
Received: from webster.rtpnc.epa.gov by merlin.rtpnc.epa.gov (8.6.9/1.34)
id IAA17770; Fri, 29 Mar 1996 08:27:43 -0500
Received: from localhost by webster.rtpnc.epa.gov (5.4R3.10T/5.40/1.0)
id AA12706; Fri, 29 Mar 1996 08:25:40 -0500
Date: Fri, 29 Mar 1996 08:25:40 -0500
Message-Id: <9603291316.AA04742@swais.access.gpo.gov>
Errors-To: richards.john@epamail.epa.gov
Reply-To: epa-pest@webster.rtpnc.epa.gov
Originator: epa-pest@unixmail.rtpnc.epa.gov
Sender: epa-pest@webster.rtpnc.epa.gov
Precedence: bulk
From: everybody <guest@swais.access.gpo.gov>
To: Multiple recipients of list <epa-pest@webster.rtpnc.epa.gov>
Subject: Trichoderma harzianum Rifai Strain KRL-AG2; Notice of filing
X-Listserver-Version: 6.0(EPA) -- UNIX ListServer by Anastasios Kotsikonas
X-Comment: U.S. EPA FEDERAL REGISTER PESTICIDE documents

[Federal Register: March 29, 1996 (Volume 61, Number 62)]
[Notices]
[Page 14098-14099]
>From the Federal Register Online via GPO Access [wais.access.gpo.gov]

ENVIRONMENTAL PROTECTION AGENCY
[PP 6F4650/PF646; FRL-5357-3]

Trichoderma harzianum Rifai Strain KRL-AG2; Notice of filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: EPA has received a petition (PP 6F4650) for a revision of the current

[[Page 14099]]
exemption from the requirement of tolerances for Trichoderma harzianum Rifai strain KRL-AG2 (40 CFR 180.1102) to include all raw agricultural commodities. The request was filed by TGT Inc., 122 North Genesee Street, Geneva, N.Y. 14456.

DATES: Written comments, identified by the docket control number [PP 6F4650/PF646], must be submitted to EPA by April 29, 1996.
ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by docket number [PP 6F4650/PF646]. No CBI should be submitted through e-mail. Electronic comments on this notice of filing may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in the SUPPLEMENTARY INFORMATION section of this document.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington DC 20460. Office location and telephone number: 5th Floor, CS #1, 2805 Jefferson Davis Hwy., Arlington, VA, 703-308-8097; e-mail address: bacchus.shanaz@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

PP 6F4650. This notice announces that EPA has received from TGT Inc., 122 North Genesee Street, Geneva, N.Y. 14456, a notice of filing under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) for pesticide petition (PP) 6F4650 to amend 40 CFR part 180 to revise the current exemption from the requirement of tolerances for the microbial pesticide Trichoderma harzianum Rifai strain KRL-AG2. The current exemption from the requirement of a tolerance (40 CFR 180.1102) is established for residues of this biofungicide in or on beans (green and dry), cabbage, corn (field and sweet), cotton, cucumbers, peanuts, potatoes, sorghum, soybeans, sugar beets, and tomatoes when used as a fungicide for the treatment of seeds of these crops in accordance with good agricultural practices.

This petition requests that the current exemption from tolerances be revised to include all raw agricultural commodities which have been sprayed or otherwise treated with Trichoderma harzianum Rifai strain KRL-AG2. The pesticide is to be applied as seed treatment, for pot filling, as a dip for cuttings and transplants, as an in-furrow spray, and as a sprayable formulation. Rates of application vary from 4 to 8 ounces per hundredweight of seed, and up to 10 pounds per acre (in furrow) for row crops at planting. Field and greenhouse crops may be sprayed at rates of 1 pound per acre and up to 5 applications per year.

A record has been established for this notice of filing under docket number [PP 6F4650/PF646] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does

not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments can be sent directly to EPA at:
opp-Docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this notice of filing, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

List of Subjects

Environmental Protection, Agricultural commodities, Pesticides and Pests, Reporting and recordkeeping requirements.

Dated: March 19, 1996.

Janet L. Anderson
Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 96-7743 Filed 3-28-96; 8:45 am]
BILLING CODE 6560-50-F

MESSAGE CONFIRMATION

APR-05 08:21 FRI

FAX NUMBER : 703-308-7026

NAME : BIOPESTICIDES

FAX NUMBER : 913157811793

PAGE : 04

ELAPSED TIME : 02'39"

MODE : G3 STD

RESULTS : O.K

§ 180.1099 Indole butyric acid (IBA); exemption from the requirement of tolerance.

Indole butyric acid is exempted from the requirement of a tolerance when used as a plant growth regulator at application rates less than 20 grams of active ingredient per acre (20 g ai/A) in or on the following raw agricultural commodities: Barley, beans, beets (sugar), broccoli, brussels sprouts, cabbage, cauliflower, corn (field, sweet, and popcorn), cotton, cucumber, grapefruit, lemons, lettuce, melons, mustard greens, oats, onions, oranges, peanuts, peppers, potatoes, rice, rye, sorghum (milo), soybeans, spinach, squash, strawberries, sugarcane, tomatoes, turnips, and wheat.

[55 FR 47475, Nov. 16, 1990]

§ 180.1100 Gliocladium virens GL-21; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biofungicide *Gliocladium virens* GL-21 in or on all raw agricultural commodities when used as a fungicide for inoculation of plant growth media in greenhouses in accordance with good agricultural practices.

[55 FR 50325, Dec. 6, 1990]

§ 180.1101 Parasitic (parasitoid) and predatory insects; exemption from the requirement of a tolerance.

Parasitic (parasitoid) and predatory insects are exempted from the requirement of a tolerance for residues when they are used in accordance with good agricultural and pest control practices to control insect pests of stored raw whole grains such as corn, small grains, rice, soybeans, peanuts, and other legumes either bulk or warehoused in bags. For the purposes of this rule, the parasites (parasitoids) and predators are considered to be species of Hymenoptera in the genera *Trichogramma*, Trichogrammatidae: *Bracon*, Braconidae: *Venturia*, *Mesostenus*, Ichneumonidae; *Anisopteromalus*, *Choetospila*, *Lariophagus*, *Dibrachys*, *Habrocytus*, *Pteromalus*, Pteromalidae; *Cephalonomia*, *Holepyris*, *Laelius*, Bethylidae; and of Hemiptera in the genera *Xylocoris*, *Lyctocoris*, and *Dufouriellus*, Anthocoridae. Whole insects, fragments, parts, and other residues of these parasites and predators remain subject to 21 U.S.C. 342(a)(3).

[57 FR 14646, Apr. 22, 1992]

§ 180.1102 Trichoderma harzianum, Rifai Strain KRL-AG2; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biofungicide *Trichoderma harzianum*, Rifai Strain KRL-AG2, in or on beans (green and dry), cabbage, corn (field and sweet), cotton, cucumbers, peanuts, potatoes, sorghum, soybeans, sugar beets, and tomatoes when used as a fungicide for the treatment of seeds of these crops in accordance with good agricultural practices.

[55 FR 50327, Dec. 6, 1990]

§ 180.1103 Isomate-C; exemption from the requirement of a tolerance.

The codling moth pheromone (Isomate-C) E,E-8,10-dodecenyl alcohol, dodecanol, tetradecanol is exempt from the requirements of a tolerance in or on all RAC's when formulated in polyethylene pheromone dispensers for use in orchards with encapsulated polyethylene tubing to control codling moth.

[56 FR 23523, May 22, 1991]

§ 180.1104 Poly(vinylpyrrolidone/1-eicosene); exemption from the requirement of a tolerance.

Poly(vinylpyrrolidone/1-eicosene) (CAS Reg. No. 28211-18-9), minimum average molecular weight 3,000, is exempted from the requirement of a tolerance when used as an inert ingredient (dispersing agent) for pesticides applied to growing crops or to raw agricultural commodities after harvest. The inert shall not constitute more than 10 percent by weight of any pesticide formulation. Registration of each new pesticide formulation incorporating this dispersing agent must be supported by residue data for the active ingredients.

[56 FR 32515, July 17, 1991]

U.S. ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON FINANCIAL MANAGEMENT CENTER
WASHINGTON, DC 20460

SCHEDULE OF COLLECTIONS
ACCOUNTING POINT 99

FROM: COLLECTIONS OFFICER Sharon Porter DATE 09/13/95

CERTIFICATE OF DEPOSIT NO. DM1430

NAME OF REMITTER	DETAIL DESCRIPTION OF PURPOSE	AMOUNT	RECD DATE	CHECK NO
TGT INC.	TOLERANCE	11150.00	09/13/95	096043

6F4650

*** TOTAL SCHEDULE: 11150.00

U.S. ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON FINANCIAL MANAGEMENT CENTER
WASHINGTON, DC 20460

SCHEDULE OF COLLECTIONS
ACCOUNTING POINT 99

Copy 10-19-95

FROM: COLLECTIONS OFFICER Sharon Porter DATE 10/15/95

CERTIFICATE OF DEPOSIT NO. D3266C

NAME OF REMITTER	DETAIL DESCRIPTION OF PURPOSE	AMOUNT	RECD DATE	CHECK NO
		4G4347		
ABBOTT LABORATORIES	TOLERANCE FEE	3425.00	10/13/95	D0042634
TGT INC.	TOLERANCE FEE	1500.00	10/13/95	096044
		6F4650		
	*** TOTAL SCHEDULE:	4925.00		

ATTACHMENT TO SECTION A

August 28, 1989

Ms. Susan Lewis
Environmental Protection Agency
Herbicide-Fungicide Branch
Office of Pesticide Programs
401 M Street S.W.
Washington, DC 20460

SUBJECT: KRL-AG2 (F-STOP Biological Fungicide)
EPA File Symbol 59441-Pending
Petition for an Exemption from Tolerance

QF3805

Dear Susan:

Eastman Kodak Company submits this petition for an exemption from the requirement of a tolerance pursuant to section 408(d)(1) of the Federal Food, Drug, and Cosmetic Act with respect to the pesticide Trichoderma harzianum. Attached to this letter is Kodak's petition for a tolerance exemption. A certified check in the amount of $8,875 has already been forwarded to the Agency; a copy of the letter transmitting the check is attached.

The data submitted herein to support the petition in Volumes IV through IX is included in the Application for Registration for Manufacturing Use Product and End Use Product.

If you have any questions, please do not hesitate to contact me at (716) 724-6819.

Respectfully submitted,

Deborah A. Mourey

DAM:brm
tolexempt

Encl.

Deborah A. Mourey
Manager, Regulatory Affairs
Plant Agriculture

10 of 13

ATTACHMENT TO
SECTION A

RECEIVED MAY 15 1995

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 28 1995

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES

TGT, Inc.
Attn: Mr. Thomas E. Stasz
122 North Genesee Street
Geneva, NY 14456

Dear Mr. Stasz:

Subject: Revised Manufacturing Process
T-22G Biological Plant Protectant Granules
EPA Reg. No: 68539-3
Submission Date: April 27, 1995

The revised manufacturing process submitted is acceptable and copies of the revised Confidential Statements of Formula have been added to the file for the subject product registration.

Sincerely,

Janet L. Andersen

Janet L. Andersen, Acting Director
Biopesticides and Pollution
Prevention Division 7501W

11 of 13

TGT Inc

Biological Technologies for the 21st Century

September 7, 1995

Environmental Protection Agency
Headquarters Accounting Operations Branch
Office of Pesticide Programs
(TOLERANCE FEES)
PO Box 360277M
Pittsburgh, PA 15251

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Dear Sirs:

Enclosed is a certified check for $11,150.00 made payable to the Environmental Protection Agency in payment of the fee for a petition to revise an Exemption from Tolerance for the biological fungicide Trichoderma harzianum Rifai strain KRL-AG2 (EPA reg. no. 68539-1; current exemption at 40 CFR 180.1102).

Also enclosed is a copy of the petition dated September 7, 1995.

If there are questions, I can be reached at 315-781-1703.

Sincerely,

Thomas E. Stasz

Thomas E. Stasz
Vice President for Legal Affairs

TES/kam
Enclosure

12 & 13

122 North Genesee Street, Geneva, New York 14456
phone (315) 781-1703 ◊ (315) 781-1793 fax

TGT Inc

Biological Technologies for the 21st Century

September 7, 1995

Document Processing Desk (PETN)
Office of Pesticide Programs (H7504C)
Environmental Protection Agency
401 M Street S.W.
Washington, DC 20460

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Attn: Mr Robert Torla

SUBJECT: Request for Refund of Petition Fee (for Exemption from Tolerance Petition) and for Refund of Request Fee

Dear Mr. Torla:

TGT, Inc. has submitted a petition, dated September 7, 1995 (copy attached) for revision of an Exemption from Tolerance for a biological fungicide, and TGT, Inc.has paid the Petition Fee of $11,150.00 (photocopy of check attached). TGT hereby requests a refund of the Petition Fee.

Also, a check for $1,500 is enclosed in payment of this request for refund as required by 40 CFR 180.33 (m). We hereby request a refund of this latter Request Fee as well.

Refund of these fees is justified and is in the public interest. A Petition Fee was paid when the original exemption from tolerance was submitted in 1989. The current Petition is merely to revise the exemption from tolerance, as was suggested by the Agency. All significant information pertaining to the present revision has already been reviewed by the agency and is available in the Data Evaluation Record. Payment of a fee at the present time to revise the exemption from tolerance amounts to a double fee. The present petition to revise the exemption from tolerance is basically a housecleaning step and will avoid repeated requests to the Agency as the registrations for end use products are expanded. We are attempting to obtain a broader exemption from tolerance, as perhaps should have been done initially.

122 North Genesee Street, Geneva, New York 14456
phone (315) 781-1703 • (315) 781-1793 fax

The subject of the Petition to revise the exemption from tolerance is a widespread and innocuous soil fungus Trichoderma harzianum strain KRL-AG2. Originally registered several years ago, this fungus has been extensively tested for environmental and toxicological safety, and all concerns by the Agency have been addressed. The benign nature of this biocontrol fungus indicates that little additional review by the Agency will be required, and that a refund of the Petition Fee is therefore justified.

It is also critically important for the development of biological fungicides for the Agency to support emerging companies by granting fee refunds. Much of the effort and expense of developing and registering biological fungicides is being expended by emerging companies, and petition fees are a significant obstacle. Biologicals can significantly reduce chemical pesticide use for plant disease control, but only if companies are able to meet formidable obstacles, including registration costs.

The petitioner, TGT Inc, is a new company formed to get biological fungicides developed by university research out into the real world. The subject of the petition is a potentially widely useful biological fungicide, Trichoderma harzianum strain KRL-AG2. Refund of the petition fee for revising the exemption will remove a major barrier in our efforts to make this biological fungicide available.

We also note that an increasing number of biological materials are entering the market without registration or safety testing by using the label "inoculant" instead of "pesticide". We do not approve of this development in the biological pesticide industry, and feel it is important for products to be registered at the Federal and state levels. Refund of the Petition and Refund Request Fees by the Agency will support our efforts to comply with all regulatory requirements and help us to compete with these "inoculant" materials.

Sincerely,

Thomas E. Stasz

Thomas E. Stasz
Vice President for Technology Development
& Legal Affairs

TES/kam
Enclosure

TGT Inc

Biological Technologies for the 21st Century

6F4650

September 7, 1995

Document Processing Desk (PETN)
Office of Pesticide Programs (H7504C)
Environmental Protection Agency
401 M Street S.W.
Washington, DC 20460

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Attn: Mr Robert Torla

SUBJECT: Request for Refund of Petition Fee (for Exemption from Tolerance Petition) and for Refund of Request Fee

Dear Mr. Torla:

TGT, Inc. has submitted a petition, dated September 7, 1995 (copy attached) for revision of an Exemption from Tolerance for a biological fungicide, and TGT, Inc.has paid the Petition Fee of $1,150.00 (photocopy of check attached). TGT hereby requests a refund of the Petition Fee.

Also, a check for $1,500 is enclosed in payment of this request for refund as required by 40 CFR 180.33 (m). We hereby request a refund of this latter Request Fee as well.

Refund of these fees is justified and is in the public interest. A Petition Fee was paid when the original exemption from tolerance was submitted in 1989. The current Petition is merely to revise the exemption from tolerance, as was suggested by the Agency. All significant information pertaining to the present revision has already been reviewed by the agency and is available in the Data Evaluation Record. Payment of a fee at the present time to revise the exemption from tolerance amounts to a double fee. The present petition to revise the exemption from tolerance is basically a housecleaning step and will avoid repeated requests to the Agency as the registrations for end use products are expanded. We are attempting to obtain a broader exemption from tolerance, as perhaps should have been done initially.

122 North Genesee Street, Geneva, New York 14456
phone (315) 781-1703 ◊ (315) 781-1793 fax

The subject of the Petition to revise the exemption from tolerance is a widespread and innocuous soil fungus, Trichoderma harzianum strain KRL-AG2. Originally registered several years ago, this fungus has been extensively tested for environmental and toxicological safety, and all concerns by the Agency have been addressed. The benign nature of this biocontrol fungus indicates that little additional review by the Agency will be required, and that a refund of the Petition Fee is therefore justified.

It is also critically important for the development of biological fungicides for the Agency to support emerging companies by granting fee refunds. Much of the effort and expense of developing and registering biological fungicides is being expended by emerging companies, and petition fees are a significant obstacle. Biologicals can significantly reduce chemical pesticide use for plant disease control, but only if companies are able to meet formidable obstacles, including registration costs.

The petitioner, TGT Inc, is a new company formed to get biological fungicides developed by university research out into the real world. The subject of the petition is a potentially widely useful biological fungicide, Trichoderma harzianum strain KRL-AG2. Refund of the petition fee for revising the exemption will remove a major barrier in our efforts to make this biological fungicide available.

We also note that an increasing number of biological materials are entering the market without registration or safety testing by using the label "inoculant" instead of "pesticide". We do not approve of this development in the biological pesticide industry, and feel it is important for products to be registered at the Federal and state levels. Refund of the Petition and Refund Request Fees by the Agency will support our efforts to comply with all regulatory requirements and help us to compete with these "inoculant" materials.

Sincerely,

Thomas E. Stasz

Thomas E. Stasz
Vice President for Technology Development
& Legal Affairs

TES/kam
Enclosure

TGT Inc

Biological Technologies for the 21st Century

September 7, 1995

Environmental Protection Agency
Headquarters Accounting Operations Branch
Office of Pesticide Programs
(TOLERANCE FEES)
PO Box 360277M
Pittsburgh, PA 15251

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Dear Sirs:

Enclosed is a certified check for $11,150.00 made payable to the Environmental Protection Agency in payment of the fee for a petition to revise an Exemption from Tolerance for the biological fungicide Trichoderma harzianum Rifai strain KRL-AG2 (EPA reg. no. 68539-1; current exemption at 40 CFR 180.1102).

Also enclosed is a copy of the petition dated September 7, 1995.

If there are questions, I can be reached at 315-781-1703.

Sincerely,

Thomas E. Stasz

Thomas E. Stasz
Vice President for Legal Affairs

TES/kam
Enclosure

122 North Genesee Street, Geneva, New York 14456
phone (315) 781-1703 ◊ (315) 781-1793 fax

BANK MONEY ORDER

096043

REMITTER TGT Inc.
Tolerance Fee

50-264/21

DATE Sept 9, 1995

PAY TO THE ORDER OF ****** U.S. Environmental Protection Agency *******

TOMPKINS COUNTY TRUST CO [illegible]

P.O. BOX 460
ITHACA, NEW YORK 14851

[illegible]

⑈096043⑈ ⑆021302648⑆01 205⑈900003⑈

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Case: 194430          °     PRAT - SUBMISSION SUBSYSTEM          °Date: 10/30/95
                      °   PRIMARY TOLERANCE PETITION CASE        °Time: 9:53 am
```

CASE INFORMATION

CASE TYPE: TOLERANCE PET NO:9F03805 ORIG ACTION:
COMPANY NO: STATUS:
CHEMICAL: 128903 Trichoderma harzianum (ATCC 20476) REGIONAL: N
USES: RAC
SUB:08/29/89 RECV:09/21/89 EFF: / / LAST EXT: / / CURR EXPR: / /
PM/RM:90 JANET ANDERSEN SAFER:
RESTRICTIONS:

SUBMISSION INFORMATION

SUB BC	ACTION	RESPONSE	APPLIED	RECEIVED	RESPONSE
S288395	230 F PET RAW AGRI COMMO	11 OBJ-DATA DEF	08/29/89	09/21/89	07/11/90
S288396	231 RESUBMISSION	41 ESTAB OF PER	07/10/90	07/11/90	11/27/90

DESC: OLTS rec 253080 EASRMAN KODAK RANKING: 0
COMM: IN TB, DEB REVIEW (F2)

```
 F1  Help °          Select Submission with light bar and press ENTER for
 F10 Error° Submission/Data Package list or press ESC for more choices °Þ°°°
```

Eastman Kodak

U.S. ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON FINANCIAL MANAGEMENT CENTER
WASHINGTON, DC 20460

SCHEDULE OF COLLECTIONS
ACCOUNTING POINT 99

FROM: COLLECTIONS OFFICER Sharon Porter **DATE** 09/13/95

CERTIFICATE OF DEPOSIT NO. DM1430

NAME OF REMITTER	DETAIL DESCRIPTION OF PURPOSE	AMOUNT	RECD DATE	CHECK NO
TGT INC.	TOLERANCE	11150.00	09/13/95	096043

6F4650

*** TOTAL SCHEDULE: 11150.00

BPD

Sue Sutton

GEH3@Cornell.edu

[redacted] FINANCIAL MANAGEMENT CENTER
WASHINGTON, DC 20460

SCHEDULE OF COLLECTIONS
ACCOUNTING POINT 99

Copy 10-19-95

FROM: COLLECTIONS OFFICER Sharon Porter DATE 10/25/95

CERTIFICATE OF DEPOSIT NO. D3266C

NAME OF REMITTER	DETAIL DESCRIPTION OF PURPOSE	AMOUNT	RECD DATE	CHECK NO
			4G4347	
ABBOTT LABORATORIES	TOLERANCE FEE	3425.00	10/13/95	D004263
TGT INC.	TOLERANCE FEE	1500.00	10/13/95	096044
			6F4650	
	*** TOTAL SCHEDULE:	4925.00		

File copy

6F4650

Cover letter to Bob Torla
(Petition & Refund request sent directly to him AND to document desk)

TGT Inc

Biological Technologies for the 21st Century

September 7, 1995

BY FEDEX

Mr. Robert Torla
OPP BPPD H7504C
Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

SUBJECT: Revision of Exemption from Tolerance for Trichoderma harzianum strain KRL-AG2

Dear Mr. Torla:

Enclosed is a petition to revise an exemption from tolerance (40 CFR 180.1102) and a request for refund of the petition and refund request fees, sent directly to you as we discussed. The petition has also been sent to the document processing desk, as you directed.

The required petition fee has been sent to the EPA, Headquarter Accounting Branch, Pittsburgh, PA (photocopy attached). The fee for the request for refund is included with the materials sent to the document processing desk (photocopy enclosed).

Thank you for your assistance with this petition and refund request. As I explained on the phone today, we need to revise the exemption and revise our product registrations to satisfy our marketing partners, and time is of the essence.

Very truly yours,

Thomas E. Stasz

Thomas E. Stasz
VP Technology Development
& Legal Affairs

TES/km
encl.

122 North Genesee Street, Geneva, New York 14456
phone (315) 781-1703 ◊ (315) 781-1793 fax

Fike copy
Pet. for Tolerance

TGT Inc

Biological Technologies for the 21st Century

September 7, 1995

sent

Document Processing Desk (PETN)
Office of Pesticide Programs H7504C
Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

(also sent by FedEx)

Attn Mr. Robert Torla

SUBJECT: Revision of Exemption from Tolerance for Trichoderma harzianum strain KRL-AG2

Dear Mr. Torla:

The undersigned, Thomas E. Stasz, submits this petition on behalf of TGT Inc., pursuant to section 408 (d) (1) of the Federal Food, Drug, and Cosmetic Act with respect to the pesticide chemical Trichoderma harzianum Rifai strain KRL-AG2.

This is a petition to revise the current exemption from tolerance (40 CFR 180.1102) to include "in or on all raw agricultural commodities"and to include additional uses, as was recommended by Mr. Carl Grable of the Agency.

The required fee has been sent to the EPA, Headquarter Accounting Branch, Pittsburgh, PA (photocopy attached).

Petitioner: TGT, Inc, 122 North Genesee Street, Geneva, N.Y. 14456

By authority of: Rustin R. Howard, President

Attached hereto, in duplicate, and constituting a part of this petition, are the following:

A. The name, chemical identity, and composition of the pesticide chemical.

1 of 13

122 North Genesee Street, Geneva, New York 14456
phone (315) 781-1703 ◊ (315) 781-1793 fax

B. The amount, frequency, and time of application of the pesticide chemical.

C. Full reports of investigations made with respect to the safety of the pesticide chemical.

D. The results of tests on the amount of residue remaining, including a description of the analytical method used.

E. Practicable methods for removing residue that exceeds any proposed tolerance.

F. Proposed tolerances for the pesticide chemical if tolerances are proposed.

G. Reasonable grounds in support of the petition.

If there are questions concerning this petition, please contact Thomas E. Stasz, Vice President for Legal Affairs, at 315-781-1703 or at TGT, Inc, 122 North Genesee St., Geneva, N.Y. 14456.

Very truly yours,

Thomas E. Stasz

Thomas E. Stasz
VP Technology Development
& Legal Affairs

TES/km

encl

2 of 13

Petition to Revise Exemption from Tolerance submitted Sept. 7, 1995 by Thomas E. Stasz, VP Legal Affairs, TGT Inc., 122 N. Genesee St., Geneva, NY 14456

SECTION A NAME, CHEMICAL IDENTITY AND COMPOSITION

NAME: *Trichoderma harzianum* Rifai strain KRL-AG2 (active ingredient)
EPA reg. no. 68539-1 (MUP)
EPA reg. no. 68539-2 (seed protectant)
EPA reg. no. 68539-3 (granular formulation)
EPA reg. no. 68539-4 (planter box formulation)

Current Exemption from Tolerance 40CFR 180.1102 (Petition submitted August 28, 1989 - see attached)

CHEMICAL IDENTITY & MANUFACTURING: Active Ingredient (studies previously submitted)

MRID #	GUIDELINE #	STUDY TITLE
41245901	151A-11	Manufacturing Process (F-Stop Biological Fungicide Concentrate)
41245902	151A-10, 151A-12 to 151A-17	Product Chemistry and Manufacturing Process (F-Stop Biological Fungicide Concentrate)

PRODUCT CHEMISTRY: Formulated products (studies previously submitted)

MRID #	STUDY TITLE
419009-01	Product Chemistry; Volume II(A), Product Identity and Manufacturing Process
419009-02	Product Chemistry; Volume II(B), Analytical Methods and Certification of Ingredient Limits
419009-03	Product Chemistry; Volume II(C), Physical and Chemical Characteristics - Color, Physical State, Odor, and pH

419009-04	Product Chemistry; Volume II(D), Physical and Chemical Characteristics - Density, Bulk Density or Specific Gravity
419009-05	Product Chemistry; Volume II(E), Physical and Chemical Characteristics - Storage Stability and Corrosion Characteristics

Note on manufacturing process (for granular formulation Reg. No. 68539-3)

An improved manufacturing process was submitted to the Agency on December 15, 1994 and approved on April 28, 1995 (letters attached).

[redacted]

COMPOSITION:

MUP (Reg. No. 68539-1) This material consists of dried biomass of *Trichoderma* grown by liquid fermentation. The composition is 98% active ingredient (dried biomass of *Trichoderma*) and 2% inert ingredients [redacted] The MUP contains at least 1 x 10^9 colony forming units of *Trichoderma* per gram dry weight.

SEED PROTECTANT

(Reg. No. 68539-2) This material is the same as the MUP - 98% active and 2% inert ingredients. The seed Protectant contains at least 1 x 10^9 colony forming units per gram dry weight.

GRANULAR

(Reg. No. 68539-3) This material consists of 1.15% active ingredient (*Trichoderma* grown on a solid matrix carrier) and 98.85% inerts ([redacted]

4 of 13

Inert ingredient information may be entitled to confidential treatment

[redacted]. The granular contains at least 1 x 10^7 colony forming units per gram dry weight.

PLANTER BOX

(Reg. No. 68539-4) This material consists of 1.15% active ingredient *Trichoderma* and 98.85% inerts [redacted] The Planter box material contains at least 1 x 10^7 colony forming units per gram dry weight.

SECTION B AMOUNT, FREQUENCY AND TIME OF APPLICATION

Seed treatment materials are applied at up to 8 oz. per hundred weight (CWT) of seed before planting.

Granular materials are applied:

Row crops (in furrow) 10 lbs./acre at planting
Turf (broadcast) up to 4 lbs./1000 sq. ft. and up to 3 applications per year.
Greenhouse (planting mix additive) up to 2 lbs./cubic yard applied at pot-filling.

Wettable powder materials:

Greenhouse (planting mix drench) up to 4 oz./cubic yard applied at pot-filling or to established plants, and up to two applications per crop.
Row crops (in-furrow spray) up to 1 lb./acre at planting.

Sprayable formulation:

Field and greenhouse crops up to 1 lb./acre and up to 5 applications/year.

5 of 13

SECTION C SAFETY OF PESTICIDE CHEMICAL (MICROBIAL PEST CONTROL AGENT).

The following studies have been submitted previously to the Agency. The applicant hereby requests waiver of additional studies, if any.

Studies previously submitted:

MRID #	GUIDELINE #	STUDY TITLE
41245903	152A-1	Toxicology Studies -- Overview
41245904	152A-10	Acute Oral Toxicity/Pathogenicity in Rats
41245905	152A-12	Acute Pulmonary Toxicity/Pathogenicity in Rats
41245907	152A-14	Primary Eye Irritation/Infection Study in Rabbits
41245908	154A-16	Avian Oral Pathogenicity/Toxicity Test
41245909	None	Drying, Milling, and Assay of *Trichoderma* (Ricerca, Inc. report in support of Acute Oral Toxicity/Pathogenicity Study in Rats. Report No. 252994E)
41245910	None	Assay of *Trichoderma* Conidia (Ricerca, Inc. report in support of Acute Pulmonary and Acute Intravenous Toxicity/Pathogenicity Studies in Rats Report Nos. 252995F and 252996G)
41245911	None	Enumeration of *Trichoderma* AG2 (Ricerca, Inc. report in support of Primary Eye Irritation/Infection Study in Rabbits. Report No. 253030S)
41245912	None	Drying, Milling, and Assay of *Trichoderma* (Ricerca, Inc. report in support of Avaian Oral Pathogenicity/Toxicity Test. Report No. 252993D)

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41245913	None	*Trichoderma harzianum* KRL-AG2: Analysis of Samples from Toxicology Batches for MPCA Potency, Bacterial Contamination, and Biocontrol Efficacy. (Cornell report in support of Acute Oral, Pulmonary, and Intravenous Toxicity Studies in Rats, Primary Eye Irritation Study in Rabbits, and Avian Oral Pathogenicity/Toxicity Test. Report Nos. 252994E, 252995F, 252996G, 253030S and 252993D)
41245914	None	Bioassay of *Trichoderma* (Ricerca, Inc. study in support of Acute Oral Toxicity/Pathogenicity Study in Rats. Report No. 252994E)
41245915	None	Bioassay of *Trichoderma* Conidia (Ricerca, Inc. study in support of Acute Pulmonary and Acute Intravenous Toxicity/Pathogenicity Studies in Rats. Report Nos. 252995F and 252996G)41245916
41245916	None	Bioassay of *Trichoderma* (Ricerca, Inc. study in support of Avian Oral Pathogenicity/Toxicity Test. Report No.282993D

SECTION D AMOUNT OF RESIDUES REMAINING AFTER APPLICATION:

Fungi in the genus *Trichoderma* are common soil inhabitants, and any residues that may result from application of *T. harzianum* strain KRL-AG2 are not a significant concern. This fungus naturally colonizes roots of plants, and population levels decrease to background levels during intercrop periods.

Further, product chemistry and toxicology data previously submitted indicate no health or environmental hazards.

Studies previously submitted:

MRID #	GUIDELINE #	STUDY TITLE
41245902 Appendix	151A-10	Overwinter Survival of *Trichoderma harzianum* KRL-AG2
NA	151A-10	Effect of Seed treatment with *Trichoderma harzianum* strain KRL-AG2 on Mycorrhiza

7 & 13

SECTION E PRACTICABLE METHODS OF REMOVING RESIDUES

Residues will be limited and are not of concern due to the nature of *Trichoderma*, its toxicity, and use pattern. Residues are not likely to occur in the majority of crops because the fungus colonizes crop roots. Therefore, methods of removing residues from crops are not necessary. In cases where residues may occur on the surface, such as crops where edible portions are grown beneath the soil surface, no health or environmental hazards are expected based on product chemistry and toxicology data submitted, and based on the ubiquitous occurrence of these fungi in agricultural soils around the world.

SECTION F PROPOSED TOLERANCE

Because this product has exhibited no toxic or pathogenic effects, TGT, Inc. hereby requests an exemption from the requirement of a tolerance pursuant to section 408 (d) (1) of the Federal Food, Drug and Cosmetic Act with respect to the pesticide *Trichoderma harzianum* Rifai strain KRL-AG2 for the following commodities:

"in or on all raw agricultural commodities"

SECTION G REASONABLE GROUNDS IN SUPPORT OF THE PETITION

An exemption from tolerance was granted for this biocontrol fungus (40 CFR 180.1102) for certain food crops on the basis of considerable toxicological and other data and based on the widespread occurrence of *T. harzianum* fungi in agricultural soils. The present petition to extend the exemption from tolerance to uses "in or on all raw agricultural commodities" follows the same rationale. The Agency, in a facsimile letter from Mr. Carle Grable dated 4/19/94 recommended that the current exemption should be revised in this way (fax attached).

This particular strain of *T. harzianum* (strain KRL-AG2) has been widely tested. No phytotoxicity has been observed in testing on a wide range of crops, application methods, and conditions. The fungus does not interfere with other beneficial soil microbes, such as mycorrhizal fungi and root nodulating bacteria. Population levels decrease overwinter to background levels.

The toxicological data which have been submitted previously for the registration of the active ingredient *Trichoderma harzianum* include reports of acute oral and other toxicology studies including wildlife studies with bobwhite quail. These reports show there is no indication of toxicity or pathogenicity. A request for a waiver of all other toxicological data requirements, if

8 of 13

any, is made based on the facts that *Trichoderma harzianum* is widespread in the environment, is innocuous, and the use patterns for these products are limited to non-aquatic uses. The acute oral toxicity /infectivity/pathogenicity studies are classified as core-minimum.

Trichoderma harzianum (KRL-AG2) does not grow at or above 37^{o}C and is not pathogenic in warm-blooded animals or birds. *Trichoderma harzianum* is not known to be pathogenic to plants or insects. This species is naturally occurring in soils throughout the world and is widely regarded as innocuous or beneficial. The proposed application method, use, and rates will not result in a sustained increase in population over naturally occurring background levels of *Trichoderma harzianum*. The proposed uses do not pose a "may effect" to any endangered or threatened animal or plant species.

Data for environmental fate are not triggered under current requirements for the proposed product since the organism is not a product of recombinant DNA technology.

The Agency issued a Pesticide Fact Sheet in November, 1990 describing this fungus as widespread and innocuous. In PR Notice 95-3, June 7, 1995, the Agency included this fungus in a list of low risk pesticides qualifying for reduced restricted entry intervals (REI's).

Use of this biocontrol fungus can reduce the need for chemical pesticides for plant disease control.

9 of 13

B. 2

TGT Inc

Biological Technologies for the 21st Century

RECEIVED
10/12/95
BPPD

September 7, 1995

6F4650

Document Processing Desk (PETN)
Office of Pesticide Programs H7504C
Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Attn Mr. Robert Torla

9F3805

SUBJECT: Revision of Exemption from Tolerance for Trichoderma harzianum strain KRL-AG2

Dear Mr. Torla:

The undersigned, Thomas E. Stasz, submits this petition on behalf of TGT Inc., pursuant to section 408 (d) (1) of the Federal Food, Drug, and Cosmetic Act with respect to the pesticide chemical Trichoderma harzianum Rifai strain KRL-AG2.

This is a petition to revise the current exemption from tolerance (40 CFR 180.1102) to include "in or on all raw agricultural commodities" and to include additional uses, as was recommended by Mr. Carl Grable of the Agency.

The required fee has been sent to the EPA, Headquarter Accounting Branch, Pittsburgh, PA (photocopy attached).

Petitioner: TGT, Inc, 122 North Genesee Street, Geneva, N.Y. 14456

By authority of: Rustin R. Howard, President

Attached hereto, in duplicate, and constituting a part of this petition, are the following:

A. The name, chemical identity, and composition of the pesticide chemical.

1 of 13

122 North Genesee Street, Geneva, New York 14456
phone (315) 781-1703 ◊ (315) 781-1793 fax

B. The amount, frequency, and time of application of the pesticide chemical.

C. Full reports of investigations made with respect to the safety of the pesticide chemical.

D. The results of tests on the amount of residue remaining, including a description of the analytical method used.

E. Practicable methods for removing residue that exceeds any proposed tolerance.

F. Proposed tolerances for the pesticide chemical if tolerances are proposed.

G. Reasonable grounds in support of the petition.

If there are questions concerning this petition, please contact Thomas E. Stasz, Vice President for Legal Affairs, at 315-781-1703 or at TGT, Inc, 122 North Genesee St., Geneva, N.Y. 14456.

Very truly yours,

Thomas E. Stasz

Thomas E. Stasz
VP Technology Development
& Legal Affairs

TES/km

encl

2 of 13

Petition to Revise Exemption from Tolerance submitted Sept. 7, 1995 by Thomas E. Stasz, VP Legal Affairs, TGT Inc., 122 N. Genesee St., Geneva, NY 14456

SECTION A NAME, CHEMICAL IDENTITY AND COMPOSITION

NAME: *Trichoderma harzianum* Rifai strain KRL-AG2 (active ingredient)
EPA reg. no. 68539-1 (MUP)
EPA reg. no. 68539-2 (seed protectant)
EPA reg. no. 68539-3 (granular formulation)
EPA reg. no. 68539-4 (planter box formulation)

Current Exemption from Tolerance 40CFR 180.1102 (Petition submitted August 28, 1989 - see attached)

CHEMICAL IDENTITY & MANUFACTURING: Active Ingredient (studies previously submitted)

MRID #	GUIDELINE #	STUDY TITLE
41245901	151A-11	Manufacturing Process (F-Stop Biological Fungicide Concentrate)
41245902	151A-10, 151A-12 to 151A-17	Product Chemistry and Manufacturing Process (F-Stop Biological Fungicide Concentrate)

PRODUCT CHEMISTRY: Formulated products (studies previously submitted)

MRID #	STUDY TITLE
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419009-02	Product Chemistry; Volume II(B), Analytical Methods and Certification of Ingredient Limits
419009-03	Product Chemistry; Volume II(C), Physical and Chemical Characteristics - Color, Physical State, Odor, and pH

419009-04	Product Chemistry; Volume II(D), Physical and Chemical Characteristics - Density, Bulk Density or Specific Gravity
419009-05	Product Chemistry; Volume II(E), Physical and Chemical Characteristics - Storage Stability and Corrosion Characteristics

Note on manufacturing process (for granular formulation Reg. No. 68539-3)

An improved manufacturing process was submitted to the Agency on December 15, 1994 and approved on April 28, 1995 (letters attached).

[redacted]

COMPOSITION:

MUP (Reg. No. 68539-1) This material consists of dried biomass of *Trichoderma* grown by liquid fermentation. The composition is 98% active ingredient (dried biomass of *Trichoderma*) and 2% inert ingredients [redacted]). The MUP contains at least 1 x 10^9 colony forming units of *Trichoderma* per gram dry weight.

SEED PROTECTANT

(Reg. No. 68539-2) This material is the same as the MUP - 98% active and 2% inert ingredients. The seed Protectant contains at least 1 x 10^9 colony forming units per gram dry weight.

GRANULAR

(Reg. No. 68539-3) This material consists of 1.15% active ingredient (*Trichoderma* grown on a solid matrix carrier) and 98.85% inerts [redacted]

4 of 13

Manufacturing process information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

[redacted]). The granular contains at least 1 x 10^7 colony forming units per gram dry weight.

PLANTER BOX

(Reg. No. 68539-4) This material consists of 1.15% active ingredient *Trichoderma* and 98.85% inerts [redacted] The Planter box material contains at least 1 x 10^7 colony forming units per gram dry weight.

SECTION B AMOUNT, FREQUENCY AND TIME OF APPLICATION

Seed treatment materials are applied at up to 8 oz. per hundred weight (CWT) of seed before planting.

Granular materials are applied:

Row crops (in furrow) 10 lbs./acre at planting
Turf (broadcast) up to 4 lbs./1000 sq. ft. and up to 3 applications per year.
Greenhouse (planting mix additive) up to 2 lbs./cubic yard applied at pot-filling.

Wettable powder materials:

Greenhouse (planting mix drench) up to 4 oz./cubic yard applied at pot-filling or to established plants, and up to two applications per crop.
Row crops (in-furrow spray) up to 1 lb./acre at planting.

Sprayable formulation:

Field and greenhouse crops up to 1 lb./acre and up to 5 applications/year.

Inert ingredient information may be entitled to confidential treatment

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SECTION C SAFETY OF PESTICIDE CHEMICAL (MICROBIAL PEST CONTROL AGENT).

The following studies have been submitted previously to the Agency. The applicant hereby requests waiver of additional studies, if any.

Studies previously submitted:

MRID #	GUIDELINE #	STUDY TITLE
41245903	152A-1	Toxicology Studies -- Overview
41245904	152A-10	Acute Oral Toxicity/Pathogenicity in Rats
41245905	152A-12	Acute Pulmonary Toxicity/Pathogenicity in Rats
41245907	152A-14	Primary Eye Irritation/Infection Study in Rabbits
41245908	154A-16	Avian Oral Pathogenicity/Toxicity Test
41245909	None	Drying, Milling, and Assay of *Trichoderma* (Ricerca, Inc. report in support of Acute Oral Toxicity/Pathogenicity Study in Rats. Report No. 252994E)
41245910	None	Assay of *Trichoderma* Conidia (Ricerca, Inc. report in support of Acute Pulmonary and Acute Intravenous Toxicity/Pathogenicity Studies in Rats Report Nos. 252995F and 252996G)
41245911	None	Enumeration of *Trichoderma* AG2 (Ricerca, Inc. report in support of Primary Eye Irritation/Infection Study in Rabbits. Report No. 253030S)
41245912	None	Drying, Milling, and Assay of *Trichoderma* (Ricerca, Inc. report in support of Avaian Oral Pathogenicity/Toxicity Test. Report No. 252993D)

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41245913	None	*Trichoderma harzianum* KRL-AG2: Analysis of Samples from Toxicology Batches for MPCA Potency, Bacterial Contamination, and Biocontrol Efficacy. (Cornell report in support of Acute Oral, Pulmonary, and Intravenous Toxicity Studies in Rats, Primary Eye Irritation Study in Rabbits, and Avian Oral Pathogenicity/Toxicity Test. Report Nos. 252994E, 252995F, 252996G, 253030S and 252993D)
41245914	None	Bioassay of *Trichoderma* (Ricerca, Inc. study in support of Acute Oral Toxicity/Pathogenicity Study in Rats. Report No. 252994E)
41245915	None	Bioassay of *Trichoderma* Conidia (Ricerca, Inc. study in support of Acute Pulmonary and Acute Intravenous Toxicity/Pathogenicity Studies in Rats. Report Nos. 252995F and 252996G)41245916
41245916	None	Bioassay of *Trichoderma* (Ricerca, Inc. study in support of Avian Oral Pathogenicity/Toxicity Test. Report No.282993D

SECTION D AMOUNT OF RESIDUES REMAINING AFTER APPLICATION:

Fungi in the genus *Trichoderma* are common soil inhabitants, and any residues that may result from application of *T. harzianum* strain KRL-AG2 are not a significant concern. This fungus naturally colonizes roots of plants, and population levels decrease to background levels during intercrop periods.

Further, product chemistry and toxicology data previously submitted indicate no health or environmental hazards.

Studies previously submitted:

MRID #	GUIDELINE #	STUDY TITLE
41245902 Appendix	151A-10	Overwinter Survival of *Trichoderma harzianum* KRL-AG2
NA	151A-10	Effect of Seed treatment with *Trichoderma harzianum* strain KRL-AG2 on Mycorrhiza

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SECTION E PRACTICABLE METHODS OF REMOVING RESIDUES

Residues will be limited and are not of concern due to the nature of *Trichoderma*, its toxicity, and use pattern. Residues are not likely to occur in the majority of crops because the fungus colonizes crop roots. Therefore, methods of removing residues from crops are not necessary. In cases where residues may occur on the surface, such as crops where edible portions are grown beneath the soil surface, no health or environmental hazards are expected based on product chemistry and toxicology data submitted, and based on the ubiquitous occurrence of these fungi in agricultural soils around the world.

SECTION F PROPOSED TOLERANCE

Because this product has exhibited no toxic or pathogenic effects, TGT, Inc. hereby requests an exemption from the requirement of a tolerance pursuant to section 408 (d) (1) of the Federal Food, Drug and Cosmetic Act with respect to the pesticide *Trichoderma harzianum* Rifai strain KRL-AG2 for the following commodities:

"in or on all raw agricultural commodities"

SECTION G REASONABLE GROUNDS IN SUPPORT OF THE PETITION

An exemption from tolerance was granted for this biocontrol fungus (40 CFR 180.1102) for certain food crops on the basis of considerable toxicological and other data and based on the widespread occurrence of *T. harzianum* fungi in agricultural soils. The present petition to extend the exemption from tolerance to uses "in or on all raw agricultural commodities" follows the same rationale. The Agency, in a facsimile letter from Mr. Carle Grable dated 4/19/94 recommended that the current exemption should be revised in this way (fax attached).

This particular strain of *T. harzianum* (strain KRL-AG2) has been widely tested. No phytotoxicity has been observed in testing on a wide range of crops, application methods, and conditions. The fungus does not interfere with other beneficial soil microbes, such as mycorrhizal fungi and root nodulating bacteria. Population levels decrease overwinter to background levels.

The toxicological data which have been submitted previously for the registration of the active ingredient *Trichoderma harzianum* include reports of acute oral and other toxicology studies including wildlife studies with bobwhite quail. These reports show there is no indication of toxicity or pathogenicity. A request for a waiver of all other toxicological data requirements, if

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any, is made based on the facts that *Trichoderma harzianum* is widespread in the environment, is innocuous, and the use patterns for these products are limited to non-aquatic uses. The acute oral toxicity /infectivity/pathogenicity studies are classified as core-minimum.

Trichoderma harzianum (KRL-AG2) does not grow at or above 37^{o}C and is not pathogenic in warm-blooded animals or birds. *Trichoderma harzianum* is not known to be pathogenic to plants or insects. This species is naturally occurring in soils throughout the world and is widely regarded as innocuous or beneficial. The proposed application method, use, and rates will not result in a sustained increase in population over naturally occurring background levels of *Trichoderma harzianum*. The proposed uses do not pose a "may effect" to any endangered or threatened animal or plant species.

Data for environmental fate are not triggered under current requirements for the proposed product since the organism is not a product of recombinant DNA technology.

The Agency issued a Pesticide Fact Sheet in November, 1990 describing this fungus as widespread and innocuous. In PR Notice 95-3, June 7, 1995, the Agency included this fungus in a list of low risk pesticides qualifying for reduced restricted entry intervals (REI's).

Use of this biocontrol fungus can reduce the need for chemical pesticides for plant disease control.

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ATTACHMENT TO SECTION A

August 28, 1989

Ms. Susan Lewis
Environmental Protection Agency
Herbicide-Fungicide Branch
Office of Pesticide Programs
401 M Street S.W.
Washington, DC 20460

SUBJECT: KRL-AG2 (F-STOP Biological Fungicide)
EPA File Symbol 59441-Pending
Petition for an Exemption from Tolerance

Dear Susan:

Eastman Kodak Company submits this petition for an exemption from the requirement of a tolerance pursuant to section 408(d)(1) of the Federal Food, Drug, and Cosmetic Act with respect to the pesticide Trichoderma harzianum. Attached to this letter is Kodak's petition for a tolerance exemption. A certified check in the amount of $8,875 has already been forwarded to the Agency; a copy of the letter transmitting the check is attached.

The data submitted herein to support the petition in Volumes IV through IX is included in the Application for Registration for Manufacturing Use Product and End Use Product.

If you have any questions, please do not hesitate to contact me at (716) 724-6819.

Respectfully submitted,

Deborah A. Mourey

DAM:brm
tolexempt

Encl.

Deborah A. Mourey
Manager, Regulatory Affairs
Plant Agriculture

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ATTACHMENT TO SECTION A

RECEIVED MAY 15 1995

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 28 1995

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES

TGT, Inc.
Attn: Mr. Thomas E. Stasz
122 North Genesee Street
Geneva, NY 14456

Dear Mr. Stasz:

Subject: Revised Manufacturing Process
T-22G Biological Plant Protectant Granules
EPA Reg. No: 68539-3
Submission Date: April 27, 1995

The revised manufacturing process submitted is acceptable and copies of the revised Confidential Statements of Formula have been added to the file for the subject product registration.

Sincerely,

Janet L. Andersen

Janet L. Andersen, Acting Director
Biopesticides and Pollution
Prevention Division 7501W

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TGT Inc

Biological Technologies for the 21st Century

September 7, 1995

Environmental Protection Agency
Headquarters Accounting Operations Branch
Office of Pesticide Programs
(TOLERANCE FEES)
PO Box 360277M
Pittsburgh, PA 15251

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Dear Sirs:

Enclosed is a certified check for $11,150.00 made payable to the Environmental Protection Agency in payment of the fee for a petition to revise an Exemption from Tolerance for the biological fungicide Trichoderma harzianum Rifai strain KRL-AG2 (EPA reg. no. 68539-1; current exemption at 40 CFR 180.1102).

Also enclosed is a copy of the petition dated September 7, 1995.

If there are questions, I can be reached at 315-781-1703.

Sincerely,

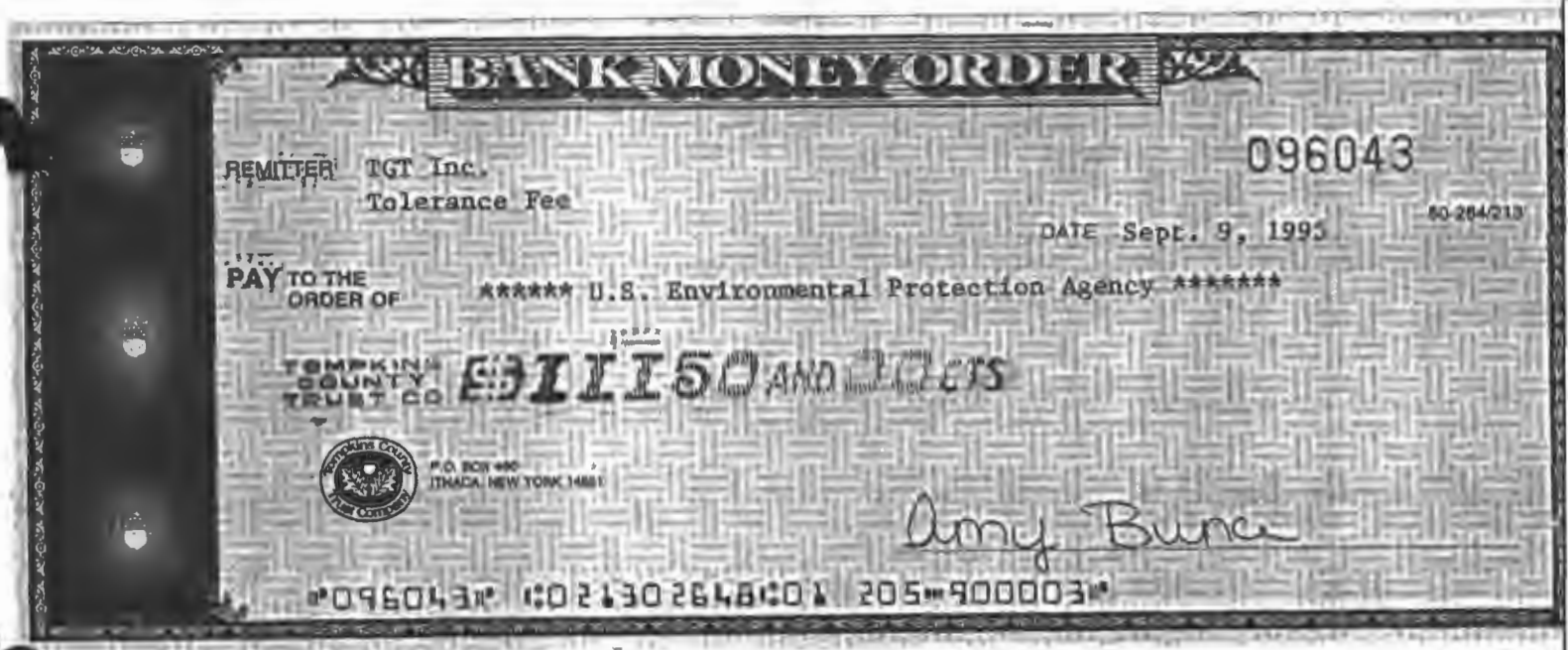
Thomas E. Stasz

Thomas E. Stasz
Vice President for Legal Affairs

TES/kam
Enclosure

12 & 13

122 North Genesee Street, Geneva, New York 14456
phone (315) 781-1703 ◊ (315) 781-1793 fax



BANK MONEY ORDER

096043

REMITTER TGT Inc.
Tolerance Fee

DATE Sept. 9, 1995

60-264/213

PAY TO THE ORDER OF ****** U.S. Environmental Protection Agency *******

TOMPKINS COUNTY TRUST CO

$111.50 AND 72 CTS

P.O. BOX 460
ITHACA, NEW YORK 14851

Amy Bunce

⑈096043⑈ ⑆021302648⑆01 205⑈900003⑈

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